

**No. 2024-1658**

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United States Court of Appeals  
for the Federal Circuit

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UNITED THERAPEUTICS CORPORATION,

*Plaintiff-Appellant,*

v.

LIQUIDIA TECHNOLOGIES, INC.,

*Defendant-Appellee,*

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*Appeal from the United States District Court for the  
District of Delaware, No. 20-755, Judge Richard Andrews*

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**APPELLEE LIQUIDIA TECHNOLOGIES, INC.'S  
NON-CONFIDENTIAL OPPOSITION TO PLAINTIFF-APPELLANT'S  
MOTION FOR A STAY  
PENDING APPEAL AND TO EXPEDITE APPEAL**

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## CERTIFICATE OF INTEREST

Counsel for Appellee certifies the following:

**1. The full name of every party represented by me is:**

Liquidia Technologies, Inc.

**2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:**

None.

**3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party represented by me are:**

Liquidia Corporation

Caligan Partners LP

**4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:**

COOLEY LLP: Sanya Sukduang, Jonathan Davies, Brittany Cazakoff

**5. The title and number of any case known to me to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal are:**

*United Therapeutics Corporation v. Liquidia Technologies, Inc.*, Nos. 2022-2217, 2023-1021 (Fed. Cir.); originating from *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1-20-cv-755 (D. Del.)

**6. Any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees):**

None.

Dated: April 26, 2024

/s/ Sanya Sukduang  
Sanya Sukduang

## TABLE OF CONTENTS

I.	FACTUAL BACKGROUND .....	2
II.	ARGUMENT .....	4
A.	UTC Is Not Likely to Succeed on the Merits .....	5
1.	FRCP 60(b) and the Hatch-Waxman Act permit the relief granted by the district court.....	6
2.	Claim cancellation is not required .....	9
3.	The '793 district court case was still pending, permitting modification of the Court's judgment .....	12
4.	Liquidia's decision to file the '793 IPR does not change the outcome here .....	14
B.	UTC Admitted It Will Not Be Irreparably Harmed .....	14
C.	The Public Interest and the Balance of Hardships Does Not Support Maintaining an Injunction Based on an Invalid Patent .....	19
D.	UTC's Appeal Does Not Need to Be Expedited.....	20
III.	CONCLUSION .....	21

## CONFIDENTIAL MATERIAL OMITTED

Pursuant to Federal Circuit Rule 25.1(e)(1)(B) and the District Court's Stipulated Protective Order in *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 20-cv-000755, Dkt. No. 33 (D.Del. Aug. 31, 2020), page 17, Exhibit 2, Exhibit 3 and its accompanying exhibits have been partially redacted. The material on these pages contains information that reveals, contains, and/or reflects information relating to marketing and business strategy plans, financial forecasts, and negotiations with payors regarding pharmaceutical pricing that United Therapeutics Corporation has designated as being confidential.

## TABLE OF AUTHORITIES

	Page(s)
<b>CASES</b>	
<i>Abbott Laboratories v. Sandoz, Inc.</i> , 544 F.3d 1341 (Fed. Cir. 2008).....	18
<i>Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.</i> , 402 U.S. 313 (1971).....	22
<i>Cap Exp., LLC v. Zinus, Inc.</i> , 996 F.3d 1332 (Fed. Cir. 2021).....	5
<i>Celsis In Vitro, Inc. v. CellzDirect, Inc.</i> , 664 F.3d 922 (Fed. Cir. 2012).....	19
<i>Commil USA, LLC v. Cisco Sys., Inc.</i> , 575 U.S. 632 (2015).....	10
<i>Cox v. Horn</i> , 757 F.3d 113 (3d Cir. 2014).....	5, 7
<i>E.I. DuPont de Nemours &amp; Co. v. Phillips Petroleum Co.</i> , 835 F.2d 277 (Fed. Cir. 1987).....	5
<i>ePlus, Inc. v. Lawson Software, Inc.</i> , 789 F.3d 1349 (Fed. Cir. 2015).....	7, 8, 14, 23
<i>Fresenius USA, Inc. v. Baxter Int'l, Inc.</i> , 721 F.3d 1330 (Fed. Cir. 2013).....	13, 14, 15, 16
<i>Horne v. Flores</i> , 557 U.S. 433 (2009).....	7
<i>In re Linerboard Antitrust Litig.</i> , 361 F. App'x 392 (3d Cir. 2010).....	5, 7
<i>Life Techs., Inc. v. Promega Corp.</i> , 189 F.R.D. 334 (D. Md. 1999).....	11
<i>Liquidia Techs., Inc. v. United Therapeutics Corp.</i> , 144 S. Ct. 873 (2024).....	3
<i>Magnesystems Inc. v. Nikken, Inc.</i> , 36 F.3d 1114, 1994 WL 492511 (Fed. Cir. Aug. 30, 1994).....	4, 5, 20
<i>MaxLinear, Inc. v. CF CRESPE LLC</i> , 880 F.3d 1373 (Fed. Cir. 2018).....	11
<i>Mendenhall v. Barber-Greene Co.</i> , 26 F.3d 1573 (Fed. Cir. 1994).....	8, 23
<i>Mylan Institutional LLC v. Aurobindo Pharma Ltd.</i> , 857 F.3d 858 (Fed. Cir. 2017).....	18
<i>People, Inc. v. Iancu</i> , 971 F.3d 1355 (Fed. Cir. 2020).....	13, 14

<i>Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.</i> , 324 U.S. 806 (1945).....	22
<i>Rufo v. Inmates of Suffolk Cnty. Jail</i> , 502 U.S. 367 (1992).....	7
<i>Sanofi-Synthelabo v. Apotex, Inc.</i> , 470 F.3d 1368 (Fed. Cir. 2006).....	18
<i>Simmons Co. v. Grier Bros. Co.</i> , 258 U.S. 82 (1922).....	16
<i>Sling TV, L.L.C. v. Realtime Adaptive Streaming, LLC</i> , 840 F. App'x 598 (Fed. Cir. 2021).....	14
<i>U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.</i> , 645 F. App'x 1026 (Fed. Cir. 2016).....	8, 22, 23
<i>U.S. v. Arthrex, Inc.</i> , 594 U.S. 1 (2021).....	13
<i>United States v. Swift &amp; Co.</i> , 286 U.S. 106 (1932).....	8
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , 74 F.4th 1360 (Fed. Cir. 2023).....	2, 12
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 23-1805, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023) .....	3, 23
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 1:23-cv-00975-RGA, Dkt. 8 (D. Del. Nov. 30, 2023).....	11
<i>XY, LLC v. Trans Ova Genetics, L.C.</i> , 890 F.3d 1282 (Fed. Cir. 2018).....	12, 13, 15

## STATUTES

21 C.F.R. §314.107(b)(3)(iii)(A).....	10
21 U.S.C. §355(c)(3)(C)(ii)(I)(aa).....	10
35 U.S.C. §315(b).....	17
35 U.S.C. §271(e)(4)(A) .....	<i>passim</i>
35 U.S.C. §315(e)(2).....	17
35 U.S.C. §318(b).....	11, 13, 14

## RULES

FRAP 41(c).....	21
FRAP 41(d) .....	21
FRCP 60 .....	7
FRCP 60(b)(5) .....	6
FRCP 60(b)(6) .....	6
FRCP 60(b)–(c) .....	5, 14

**TABLE OF ABBREVIATIONS**

United Therapeutics Corporation	UTC
Liquidia Technologies, Inc.	Liquidia
U.S. Patent No. 10,716,793	'793 patent
Final Written Decision	FWD
Food and Drug Administration	FDA
<i>Inter Partes</i> Review	IPR
New Drug Application	NDA
Pulmonary Arterial Hypertension	PAH
Patent Trial and Appeals Board	PTAB
Federal Rules of Civil Procedure	FRCP
Federal Rules of Appellate Procedure	FRAP

<b>Table of Exhibits</b>	
<b>Ex.1</b>	Stipulation and Order of Partial Dismissal Without Prejudice, <i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , No. 1:23-cv-00975, Dkt. 17 (D. Del. Jan. 22, 2024)
<b>Ex.2</b>	UTC September 2023 Forecast relied upon by UTC Declarant Dr. Selck
<b>Ex.3</b>	Declaration of Douglas Kidder

Appellant UTC seeks to unlawfully reinstate an injunction enjoining the FDA from granting final approval of Liquidia's NDA for Yutrepia™ until the expiration of the '793 patent—a patent this Court has affirmed is invalid after considering UTC's appeal on the merits and denying UTC's request for panel and en banc rehearing. UTC ignores the district court's discretionary powers under Federal Rule of Civil Procedure 60(b) to modify its judgments, overlooks provisions of the Hatch-Waxman Act precluding injunctions based on an invalid patent, and disregards the fundamental legal and equitable principle that an injunction cannot be premised on an invalid patent.

UTC originally obtained a Hatch-Waxman statutory injunction under 35 U.S.C. §271(e)(4)(A) preventing the FDA from granting final approval of Liquidia's NDA for Yutrepia™ until expiration of the '793 patent. This Court later affirmed the invalidity of the '793 patent and thus, under the same Hatch-Waxman statutory scheme, the District of Delaware correctly modified its judgment under Rule 60(b), lifting the Hatch-Waxman injunction. UTC's stay motion rests entirely on attorney argument as UTC points to no procedure or precedent establishing the district court abused its discretion or that it would likely succeed on the merits of this appeal. Moreover, UTC put itself in this position as it could have sought a stay of this Court's mandate or sought to expedite its petition for certiorari to the Supreme Court. UTC



did neither. For the reasons presented herein, UTC's motion for a stay and to expedite briefing should be denied.

## **I. FACTUAL BACKGROUND**

In January 2020, Liquidia submitted an NDA to the FDA seeking approval to market Yutrepia™, its product for the treatment of PAH. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1364 (Fed. Cir. 2023). Shortly after, UTC sued Liquidia asserting infringement of several patents, including the '793 patent. *Id.* After trial, the Court entered judgment on September 9, 2022, finding that the asserted claims of the '793 patent were valid and Liquidia induced infringement of those claims. The Court also ordered that, under 35 U.S.C. §271(e)(4)(A), “the effective date of any final approval by the FDA of Liquidia’s New Drug Application No. 213005 shall be a date which is not earlier than the expiration date of the '793 patent.” Rsp.Add2, ¶4.<sup>1</sup> Liquidia appealed this judgment. Subsequently, this Court affirmed the district court’s decision regarding the '793 patent on July 24, 2023. *United Therapeutics*, 74 F.4th at 1374. The Supreme Court denied Liquidia’s petition for a writ of certiorari in February 2024. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, 144 S. Ct. 873 (2024).

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<sup>1</sup> Citations to “Rsp.Add” are to the responsive Addendum filed herewith.

While the district court action was pending, Liquidia submitted an IPR petition regarding the '793 patent on January 7, 2021. The '793 IPR was instituted, and the PTAB issued its FWD on July 19, 2022, finding all claims of the '793 patent invalid, a month before the district court rendered its decision in the parallel action. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 23-1805, 2023 WL 8794633, at \*1 (Fed. Cir. Dec. 20, 2023). UTC appealed the FWD to this Court, which affirmed the invalidity ruling in a non-precedential opinion issued on December 20, 2023. *Id.*, \*3–6. UTC's petitions for panel rehearing and rehearing en banc were denied, and the mandate issued to the PTAB on March 19, 2024.

Shortly after this Court's decision affirming the '793 patent invalidation in the IPR, on December 26, 2023, Liquidia filed its motion for post-judgment relief under Rule 60(b), requesting the district court lift its §271(e)(4)(A) injunction. Rsp.Add4–106. UTC opposed, and Liquidia filed its reply on January 23, 2024. Rsp.Add107–144. Briefing on Liquidia's Rule 60(b) motion was complete by January 2024, prior to the Supreme Court's February 2024 denial of Liquidia's certiorari petition. The district court granted Liquidia's Rule 60(b) motion on March 28, 2024, and issued an Amended Judgment on the same day. Add5-13.

UTC then, on April 1, 2024, moved to stay entry of the Amended Judgment. Rsp.Add147–165. Liquidia opposed, and UTC submitted a reply. Rsp.Add166–204. The district court denied UTC's motion to stay on April 17, 2024. Add14–17.

## II. ARGUMENT

In determining whether to grant a stay pending appeal, UTC bears the burden of establishing the following four factors: (1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *See Magnesystems Inc. v. Nikken, Inc.*, 36 F.3d 1114, 1994 WL 492511, at \*2 (Fed. Cir. Aug. 30, 1994) (unpublished opinion). The Court further “assesses [the] movant’s chances for success on appeal and weighs the equities as they affect the parties and the public.” *E.I. DuPont de Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987). “[G]eneralized statements with no specific support” are insufficient to carry a movant’s “burden of showing irreparable harm.” *Magnesystems*, 36 F.3d at \*3.

For likelihood of success on the merits, the Court must consider the underlying issue—the district court’s grant of Liquidia’s Rule 60(b) motion. Relief under Rule 60(b) is a procedural issue on which this Court applies regional circuit law. *Cap Exp., LLC v. Zinus, Inc.*, 996 F.3d 1332, 1338 (Fed. Cir. 2021). In the Third Circuit, a district court’s decision to grant Rule 60(b) relief is reviewed for abuse of discretion. *See In re Linerboard Antitrust Litig.*, 361 F. App’x 392, 398 (3d Cir. 2010); *Cox v. Horn*, 757 F.3d 113, 124 (3d Cir. 2014)

### **A. UTC Is Not Likely to Succeed on the Merits**

The district court premised its decision to amend its judgment on Federal Rule of Civil Procedure 60(b), which places no restriction on the type of judgment from which relief can be sought, nor a specific time limit, other than “within a reasonable time,” in which such relief can be requested. Add6–9; FRCP 60(b)–(c). Not surprisingly, UTC ignores Rule 60(b) because it has no argument that the district court abused its discretion under that rule. Instead, UTC bases its motion to stay on the unsupported position that statutory injunctions, like a Hatch-Waxman injunction, cannot be modified *unless* the case is still pending *and* until patent claims are canceled by the PTO Director. *See* Dkt. 10 (“Mot.”), 8–9.

UTC fares no better with substantive patent law or the Hatch-Waxman Act, as neither supports the position that a statutory Hatch-Waxman injunction *cannot* be modified if a case is terminated and until patent claims are cancelled.<sup>2</sup> While UTC’s Motion is long on attorney argument, it is short on any precedent establishing the district court abused its discretion in vacating its prior §271(e)(4)(A) injunction under Rule 60(b). The ’793 patent was finally adjudicated invalid for Hatch-Waxman purposes when this Court affirmed the PTAB’s ’793 patent FWD on

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<sup>2</sup> The underlying district court case was still pending at the time of Liquidia’s Rule 60(b) motion. *See* §I, *supra*.

December 20, 2023, and as of that date, the district court’s Hatch-Waxman injunction could not be maintained.

**1. FRCP 60(b) and the Hatch-Waxman Act permit the relief granted by the district court**

Rule 60(b)(5) permits relief from judgment if “the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable[.]” FRCP 60(b)(5). Further, Rule 60(b)(6) grants a court the power to vacate a judgment for “any other reason that justifies relief.” FRCP 60(b)(6). The scope of Rule 60(b) is broad, authorizing “a court to grant relief from a final judgment if ‘applying [the order] prospectively is no longer equitable’ or for ‘any other reason that justifies relief.’” *In re Linerboard*, 361 F. App’x at 397 (quoting FRCP 60(b)(5)–(6)); *Cox*, 757 F.3d at 122 (“The fundamental point of 60(b) is that it provides ‘a grand reservoir of equitable power to do justice in a particular case.’”) (citation omitted). Indeed, Rule 60(b) allows a party to ask a court to modify a judgment if a significant change either in facts or in law “renders continued enforcement ‘detrimental to the public interest[.]’” *Horne v. Flores*, 557 U.S. 433, 447 (2009) (quoting *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992)); *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1354, 1355 (Fed. Cir. 2015) (“A continuing decree of injunction directed to events to come is subject always to adaptation as events may shape the need .... [A] court does not abdicate its power to revoke or modify its

mandate, if satisfied that what it has been doing has been turned through changing circumstances into an instrument of wrong.”) (quoting *United States v. Swift & Co.*, 286 U.S. 106, 114–15 (1932)).

Here, patent invalidity is a circumstance warranting relief from judgment under Rule 60(b). This Court has long recognized that an injunction based on an invalid patent cannot be maintained. *See ePlus*, 789 F.3d at 1354 (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1578 (Fed. Cir. 1994) (upholding the injunction would be “anomalous in the extreme in connection with patents this court has just held invalid.”); *U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, 645 F. App’x 1026, 1029 (Fed. Cir. 2016) (enforcing an invalid patent “would thus extend the patent beyond its proper scope.”). UTC does not assert the ’793 patent is still valid—it cannot—and thus, under this Court’s precedent, the ’793 patent cannot lawfully enjoin the FDA or any other party.

UTC points to the fact that the district court’s prior injunction under §271(e)(4)(A) was statutorily based. Mot., 9-10. Importantly, nothing in Rule 60(b) limits its reach to only discretionary, as opposed to statutory, injunctions. *See* FRCP 60. In fact, the Advisory Committee Notes make clear that “if these various amendments, including principally those to Rule 60(b), accomplish the purpose for which they are intended, *the federal rules will deal with the practice in every sort of*

*case in which relief from final judgments is asked*, and prescribe the practice.” FRCP 60 Advisory Committee’s Notes to 1946 Amendment.<sup>3</sup> Thus, it does not matter for Rule 60(b) purposes that the injunction was statutorily based; the district court properly exercised its discretion to modify its prior §271(e)(4)(A) injunction.

The Hatch-Waxman Act also dictates this outcome. UTC is correct that when the district court found the ’793 patent valid and infringed, it was required to issue an injunction under §271(e)(4)(A). But as the district court properly noted, an injunction under §271(e)(4)(A) requires an infringed patent, as an invalid patent cannot be infringed. Add8–9; *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644 (2015). Consistent with this, the statute compels that FDA grant final approval of a 505(b)(2) NDA (like Liquidia’s) on “the date on which the court of appeals decides that the patent is invalid[.]” *See* 21 U.S.C. §355(c)(3)(C)(ii)(I)(aa); *see also*, 21 C.F.R. §314.107(b)(3)(iii)(A) (calling for FDA approval on “[t]he date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid...”). Thus, even if the Court were to ignore Rule 60(b), which it should not, statutory interpretation of the Hatch-Waxman Act does not lead to UTC’s success.

UTC also cites the Orange Book Transparency Act of 2020 to support its position. Mot., 12. But the cited portions address de-listing of a patent from the

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<sup>3</sup> All emphasis added unless otherwise noted.

Orange Book. *Id.* Orange Book de-listing is not a predicate for final FDA approval or Rule 60(b) relief.<sup>4</sup> Moreover, if the Court grants UTC’s requested stay, Liquidia would be the only manufacturer that would be precluded from obtaining FDA approval because of the invalid ’793 patent—UTC would be estopped from asserting the patent against any other manufacturer. *See Life Techs., Inc. v. Promega Corp.*, 189 F.R.D. 334, 338 (D. Md. 1999) (remarking that the defendant would be the only competitor unable to practice the unenforceable patent.)

## 2. Claim cancellation is not required

Citing 35 U.S.C. §318(b), UTC asserts that “[a]n issued patent *remains in force unless and until*,” the PTO Director cancels the claims. Mot., 10 (quoting 35 U.S.C. §318(b)). UTC claims because the ’793 patent “remains in force” until cancellation, the district court had no right to modify its judgment. Mot., 11–12.

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<sup>4</sup> UTC asserts that until a patent is de-listed from the Orange Book, “a claim for patent infringement may still be pursued.” Mot., 12. Not so. If an Orange Book listed patent is found invalid, no Rule 11 basis exists to assert infringement, even if the patent has not yet been de-listed. *See MaxLinear, Inc. v. CF CRESPE LLC*, 880 F.3d 1373, 1376 (Fed. Cir. 2018) (“[A]s a result of collateral estoppel, a judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent.”) (citation omitted). UTC’s actions concerning the ’793 patent prove this point. In a related proceeding, UTC again asserted the ’793 patent against Liquidia. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, No. 1:23-cv-00975-RGA, Dkt. 8 (D. Del. Nov. 30, 2023). After this Court affirmed the ’793 patent’s invalidity on December 20, 2023, UTC dismissed its ’793 patent infringement allegations on January 22, 2024, even though at that time, this Court had not yet issued its ’793 IPR mandate, the PTO Director had not yet cancelled the claims, and the patent had not been de-listed from the Orange Book. Ex.1.



Section 318, however, states no such thing, and UTC’s unsupported interpretation runs counter to this Court’s precedent in *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282 (Fed. Cir. 2018). There, the Court made clear that “an affirmance of an invalidity finding, whether from a district court *or the Board*, has a collateral estoppel effect on all pending or co-pending actions[,]” and such effect was “immediate.” *Id.*, 1294; *see also United Therapeutics*, 74 F.4th at 1372 (“[A]n IPR decision does not have collateral estoppel effect until that decision is affirmed or the parties waive their appeal rights.”)<sup>5</sup>. Because affirmance of the PTAB’s IPR FWD takes immediate effect, claim cancellation is not required to modify a judgment under Rule 60(b) based on that same patent. While the ’793 patent claims may not yet be cancelled, the ’793 patent is invalid and under the law cannot be the basis for an injunction, whether discretionary or statutorily based *against any entity*. UTC’s actions against Liquidia prove this true. *See* n.2, *supra*.

Moreover, that the ’793 patent claims have not yet been cancelled does not negate the immediate preclusive effect of this Court’s prior decision nor prevent modification of the district court’s judgment under Rule 60(b). In *XY*, this Court dismissed a co-pending appeal on the same day it issued its affirmance of the

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<sup>5</sup> UTC also cites this Court’s decision in *United Therapeutics* for support. Mot., 11. At the time of the Court’s decision, the ’793 patent FWD had not yet been affirmed, which stands in contrast to the facts here. *United Therapeutics*, 74 F.4th at 1372.

PTAB’s IPR decision on that same patent—it did not wait for any decision on a petition for a writ of certiorari or for claim cancellation by the PTO. *XY*, 890 F.3d at 1294. And the district court properly interpreted and applied the *XY* decision when modifying its injunction. *Add8* (citing *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 721 F.3d 1330, 1344 (Fed. Cir. 2013) (“[T]here is no basis for distinguishing between the effects of a final, affirmed court decision determining invalidity and a final, affirmed PTO decision determining invalidity on a pending litigation.”)). Nonetheless, claim cancellation under §318(b) is a “nondiscretionary formality[,]” that does not impact the binding effects of the decision itself. *Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1361 (Fed. Cir. 2020) (citing 35 U.S.C. §318(b)); *see also U.S. v. Arthrex, Inc.*, 594 U.S. 1, 15 (2021) (noting PTO Director’s power under §318(b) “is limited to carrying out the ministerial duty that he ‘shall issue and publish a certificate’ canceling or confirming patent claims”); *Sling TV, L.L.C. v. Realtime Adaptive Streaming, LLC*, 840 F. App’x 598 (Fed. Cir. 2021) (describing claim cancellation under §318(b) as a “ministerial act”). For purposes of judicial review, “the certificate of cancellation is irrelevant to the finality of the agency’s action, as no agency decision-making is involved in deciding to issue the certificate.” *Sec. People*, 971 F.3d at 1361.

Citing *ePlus* and *Fresenius*, UTC continues to argue judgment cannot be modified until claims have been cancelled. *Mot.*, 11-12. But those cases hold no

such thing. In *ePlus*, while the claims had been cancelled at the time of the appeal, the Court, in recounting the long-standing judicial precedent setting aside an injunction and in agreement with Liquidia’s argument here, stated “[o]ur court has applied these principles to an injunction barring infringement of patents later found to be invalid.” 789 F.3d at 1355. In *Fresenius*, the parties disputed the effect of claim cancellation on the district court and the Court considered whether “the cancellation of claims by the PTO is binding in pending district court infringement litigation.” 721 F.3d at 1336. This is not the issue here. UTC cites no case holding that modification of a judgment under Rule 60(b) was improper *because* patent claims had not yet been cancelled.

### **3. The ’793 district court case was still pending, permitting modification of the Court’s judgment**

Pointing to *XY*, UTC asserts the district court erred because an appellate decision affirming a PTAB’s invalidity decision only has preclusive effect on “pending or co-pending actions involving the patent[,]” but no effect on “terminated” cases. Mot., 14 (quoting *XY*, 890 F.3d at 1294). But at the time of this Court’s ’793 IPR affirmance in December 2023, Liquidia’s petition for certiorari was pending, and thus the underlying district court case had not been terminated. Mot., 5–6; Add5–6. Moreover, briefing on Liquidia’s Rule 60(b) motion concluded January 23, 2024, again during the pendency of the district court action. Rsp.Add129–144. Thus, the district court’s judgment could be modified because it

“was still under judicial consideration.” Add16–17. UTC cites no authority to support its position otherwise.

UTC’s suggestion that this Court’s earlier affirmance of the ’793 patent’s validity should take precedence over this Court’s later ’793 IPR affirmance has already been rejected by this Court. Mot., 15. In *Fresenius*, patent owner Baxter made a similar argument to UTC’s, arguing that the Court’s prior affirmance of validity of the patent at issue should preclude application of a later decision invalidating the same patent. 721 F.3d at 1334, 1340. Relying on the Supreme Court’s decision in *Simmons Co. v. Grier Bros. Co.*, 258 U.S. 82 (1922), the *Fresenius* court disagreed, stating “the district court must apply intervening legal developments affecting the asserted patent’s validity, even if the court of appeals already decided the validity issue the other way.” 721 F.3d at 1342. While the *Simmons* decision benefitted the patent owner, the *Fresenius* decision said the same rules apply when the “beneficiary is the alleged infringer.” *Id.* at 1343. Here, because Liquidia’s certiorari petition was still pending at the time of the ’793 IPR affirmance and briefing on the Rule 60(b) issue, the district court properly exercised its discretion and modified its judgment.

Even if the underlying district court case had been terminated, the district court could still properly exercise its discretion and modify its §271(e)(4)(A) judgment. Nothing in Rule 60 requires a pending case, and relief under Rule

60(b)(5)–(6) may be brought “within a reasonable time.” FRCP 60(b)–(c). To suggest an injunction can only be modified if a case is still pending would not only be inconsistent with the language of Rule 60(b) but also eviscerate its very purpose.

**4. Liquidia’s decision to file the ’793 IPR does not change the outcome here**

UTC attempts to make much of the fact that the invalidation of the ’793 patent, and this Court’s subsequent affirmance, stems from an IPR FWD. Mot., 2, 8, 10, 13. But UTC cites no authority to support its position that Liquidia’s decision to bring an IPR proceeding prevents the district court from modifying its judgment under Rule 60(b). Congress intended IPRs to take place concurrently with district court proceedings. *See, e.g.*, 35 U.S.C. §§315(b) (requiring IPR to be sought within one year of service of a patent infringement complaint), 315(e)(2) (precluding assertion of invalidity grounds in district court that could have raised in the IPR). There is nothing in the statute, legislative history, or case law suggesting Congress intended to penalize entities filing IPRs. To penalize Liquidia’s choice of procedure discourages future litigants from pursuing an IPR, increasing the burden on district courts and costs on the parties.

**B. UTC Admitted It Will Not Be Irreparably Harmed**

UTC’s allegations of irreparable harm ring hollow. Mot., 16-19. UTC alleges that it will suffer irreparable harm having to “directly compete with an infringer[.]” *Id.*, 17 (citation omitted). Setting aside the fact that the ’793 patent is invalid and

cannot be infringed, UTC’s CEO, Dr. Rothblatt admitted in 2023 that Liquidia’s Yutrepia™ “***does not challenge our projected double-digit growth.*** It’s because it’s not a generic product, but is instead ***a strongly differentiated drug device product[.]***” Rsp.Add173. Dr. Rothblatt also told shareholders “there is so much robust room for growth and improvement in pulmonary hypertension[.]” and that UTC “welcome[s] any new agent that can help the health of the pulmonary hypertension patient population[.]” which necessarily includes Yutrepia™. Rsp.Add192. And to emphasize her point, Dr. Rothblatt added that “the experience has been that when new agents have been introduced into the market, ***it has grown the market*** for all of the existing patients.” *Id.* Thus, rather than believe attorney argument, shielded from public scrutiny, that UTC will suffer irreparable harm, the Court should give weight to the real-world public statements from UTC’s CEO that new products like Yutrepia™ pose no danger to UTC’s bottom line.

The cases UTC cites, including *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 863 (Fed. Cir. 2017); *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1343 (Fed. Cir. 2008); and *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1373–74 (Fed. Cir. 2006) all involve the harm associated with generic substitution of a branded product. As UTC publicly acknowledged, Yutrepia™ is “not a generic product,” and thus these cases are inapplicable. Rsp.Add173. UTC’s reliance on *Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930-31 (Fed. Cir.

2012), is also misplaced because in that case, Celsis *actually* modified its pricing whereas UTC presented no evidence that it will do so here.

UTC also contends that it may suffer “lost sales, lost research and development, [and] price erosion.” Mot., 17-18 (citation omitted). But UTC cites no evidence in support. Indeed, UTC never states that sales *will* be lost or prices *will* be eroded if Yutrepia™, a “differentiated drug device product,” enters the market. Rsp.Add173. Rather than establishing irreparable harm, UTC submitted a speculative declaration from Dr. Selck. *See* Mot. Ex.1. Dr. Selck’s declaration was not before the district court and instead submitted for the first time on appeal.<sup>6</sup> If UTC believed that Dr. Selck’s declaration was pertinent to its claims of irreparable harm here, UTC could have submitted it for consideration and fact finding by the district court judge, but tellingly chose not to.

Dr. Selck’s declaration is nevertheless unhelpful, as he provides no evidence from UTC that UTC *will* lower its prices, *will* increase discounts in response to Liquidia’s launch, or *will* lose sales. Dr. Selck, at most, speculates as to UTC’s harm by footnoting undocumented, two-month old “interviews” with UTC employees that neither Liquidia, nor this Court, can verify. *See e.g.*, Mot. Ex.1 at 32 nn.151–152;

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<sup>6</sup> UTC cited to a Selck declaration in support of its district court motion to stay, but that declaration was not of record and addressed a preliminary injunction motion involving a different patent. Add210.

Ex.3, ¶¶8, 59–63. In short, UTC’s motion provides nothing more than generalized allegations of economic harm based on cases concerning generic drug entry, which are not the facts here. Ex.3, ¶¶7–9, 28–45, 59–65; *see Magnesystems*, 36 F.3d at \*3 (“generalized statements with no specific support” are insufficient to carry a movant’s “burden of showing irreparable harm.”).

Moreover, the information underlying Dr. Selck’s declaration belies any claim of price erosion or lost sales. He relies upon a September 6, 2023<sup>7</sup> “United Therapeutics Tyvaso Forecast (2023-2035)” which provides a forecast of UTC’s anticipated sales of the Tyvaso products that compete with Liquidia’s Yutrepia™. Ex.2. UTC’s forecast, which expressly acknowledges UTC’s market information with market information in 2024, shows unabated market projections in (1) the number of patients treated with Tyvaso products (“Tyvaso Treated Patients”) from market projections in year to market projections in year, (2) the net price of Tyvaso products (“Net Pricing” of Tyvaso TD-300 and Tyvaso DPI) market projections and (3) net revenue from Tyvaso sales (“Tyvaso WHO GROUP 1 (PAH)” and “Tyvaso WHO GROUP 3 (PH-ILD)”) market projections from market projections in year to over market projections in year Ex.2 at 1–2; Ex.3, ¶¶30–39. This is consistent with the statements of UTC’s CEO that when new products are introduced, “it has grown

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<sup>7</sup> The date of the forecast is identified in Dr. Selck’s materials considered list. Mot. Ex.1, Att. A-2 at 18.



the market[.]” Add192. There is no sound basis for Dr. Selck to assume that UTC will suffer any lost sales or price erosion due to the launch of Yutrepia™.

UTC’s allegations, sealed from public scrutiny, are further undermined by public statements made just weeks ago in **March 2024** by Michael Benkowitz, UTC’s President and COO, that even with Liquidia competition, UTC will still achieve its goal of a “\$4 billion run rate by mid-decade” and is confident that Liquidia and UTC will compete on “a level playing field.” Rsp.Add197, Rsp.Add200. These are not statements made by a company that believes it will suffer any harm. Indeed, a few weeks later, UTC announced a \$1 billion “share repurchase program” that was based on “the strength of United Therapeutics’ balance sheet and confidence in its near term prospects.” Rsp.Add205.

Finally, UTC contends that Liquidia “likely would be unable to pay UTC’s full monetary damages.” Mot., 19. But this argument runs counter to UTC’s later position that Liquidia “‘is very well capitalized[.]’ and has ‘never been in a stronger position[.]’” *Id.*, 20; Rsp.Add151. Moreover, even in the unlikely event the Supreme Court grants certiorari from this Court’s unanimous, non-precedential decision that was not reheard by the panel or en banc affirming the invalidity of the ’793 patent, that process will be sufficiently short-lived that even if the Supreme Court reverses, Liquidia will be able to pay UTC’s alleged monetary damages. Ex.3, ¶¶90–94.

**C. The Public Interest and the Balance of Hardships Does Not Support Maintaining an Injunction Based on an Invalid Patent**

“A patent by its very nature is affected with a public interest” and “[t]he far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies ... are kept within their legitimate scope.” *Blonder-Tongue Lab’ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 343 (1971) (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 US. 806, 816 (1945)). The district court served the public interest by lifting the Hatch-Waxman injunction. Had it not, the district court would have been extending the invalid ’793 patent beyond its proper scope. *See U.S. Ethernet*, 645 F. App’x at 1029. Indeed, as the district court recognized, the public interest is not served by maintaining an injunction based on an invalid patent. *Add17 n.2; Mendenhall*, 26 F.3d at 1578 (upholding an injunction would be “anomalous in the extreme in connection with patents this court has just held invalid.”); *ePlus*, 789 F.3d at 1354–55 (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *U.S. Ethernet*, 645 F. App’x at 1029.

Here, UTC’s assertions that the balance of hardships and public interest warrant granting its requested stay should be rejected as they were by the district court. *Mot.*, 19-20; *Rsp.Add151; Add15-16*. Further, UTC’s assertion that the value of the ’793 patent would be undermined by permitting “Liquidia to launch ***on the basis of an administrative decision***” belittles this Court’s affirmance of the PTAB’s

'793 patent FWD and subsequent denial of UTC's rehearing requests. Mot., 21. Finally, granting UTC's requested stay would only prolong the harm already suffered by Liquidia, as the '793 patent has been invalid since July 19, 2022, when the PTAB issued its FWD, which was affirmed by this Court four months ago on December 20, 2023. *See United Therapeutics*, 2023 WL 8794633, at \*1. Because, in UTC's words, Liquidia's launch will not challenge UTC's "*projected double-digit growth*[" the balance of hardships favors Liquidia, not UTC. *See* Rsp.Add168, Rsp.Add173.

**D. UTC's Appeal Does Not Need to Be Expedited**

UTC requested the Court expedite Liquidia's merits responsive brief by 10 days. Mot., 22. It appears the Court denied UTC's request. *See* Dkt. 12, 2. To the extent the Court reconsiders, UTC's request should be denied. Expedited proceedings are not routinely granted (*see* Fed. Cir. R. 27, Prac. Note), and if UTC believes time is of the essence, it can file its opening brief before May 15, 2024. Indeed, UTC acknowledged the "limited nature of the issues in this appeal," and appears to have already presented its primary arguments in this motion. Mot., 22. UTC also contends its harm will be "compound[ed]" if briefing is not expedited and the FDA grants final approval. *Id.*, 21. But UTC suffers no more harm than any Hatch-Waxman plaintiff whose patent has been invalidated and affirmed on appeal.

Moreover, UTC put itself in this situation. If it truly believed it had a meritorious petition to the Supreme Court presenting a substantial question *and* good cause existed, it could have sought a stay of this Court’s PTAB mandate while it sought Supreme Court review. *See* FRAP 41(d) (a motion to stay pending certiorari petition “must show that the petition would present a substantial question and that there is good cause for a stay”). It did not, and the mandate became immediately effective when it issued on March 19, 2024. FRAP 41(c). Finally, expediting would be prejudicial to Liquidia. UTC filed its notice of appeal on March 28, giving itself 48 days to file its opening brief, but requests Liquidia respond in only 30. And only now, 10 days later, did UTC first raise the issue of expedited briefing. Simultaneously, UTC intends to take its time, until June 2024, in petitioning the Supreme Court. Urgency is not UTC’s concern and for these reasons, any renewed request that Liquidia expedite its merits response should be denied.

### III. CONCLUSION

For the foregoing reasons, UTC’s motion for a stay and to expedite briefing should be denied.

Dated: April 26, 2024

Respectfully submitted,

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# **ADDENDUM**

**ADDENDUM TABLE OF MATERIALS**

<b>Dkt.</b>	<b>Date</b>	<b>Description</b>	<b>Page No.</b>
436	9/9/2022	Final Judgment	<b>Add1</b>
462	12/26/2023	Liquidia's Brief in Support of Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b)	<b>Add4</b>
		Exhibit 1	<b>Add18</b>
		Exhibit 2	<b>Add32</b>
		Exhibit 3	<b>Add82</b>
		Exhibit 4	<b>Add88</b>
465	1/16/2024	UTC's Answering Brief in Opposition to Liquidia Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b)	<b>Add107</b>
466	1/23/2024	Liquidia's Reply Brief in Support of Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b)	<b>Add129</b>
482	3/28/24	UTC's Letter Brief in Support of Motion to Stay	<b>Add147</b>
		Exhibit A	<b>Add153</b>
		Exhibit B	<b>Add161</b>
487	4/4/2024	Liquidia's Letter Brief in Opposition of Motion to Stay	<b>Add166</b>
		Exhibit 1	<b>Add170</b>
		Exhibit 2	<b>Add182</b>
		Exhibit 3	<b>Add194</b>
	3/25/2024	Press Release: "United Therapeutics Corporation Announces \$1 Billion Accelerated Share Repurchase Program," available at <a href="https://ir.unither.com/press-releases/2024/03-25-2024-110046740">https://ir.unither.com/press-releases/2024/03-25-2024-110046740</a>	<b>Add205</b>

485	04/01/2024	UTC's Letter Brief in Support of Motion to Stay	<b>Add207</b>
		Exhibit A	<b>Add213</b>
		Exhibit B	<b>Add221</b>



IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)	
CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-755 (RGA) (JLH)
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

**FINAL JUDGMENT**

At Wilmington, Delaware, this 9<sup>th</sup> day of September, 2022:

**WHEREAS**, Plaintiff United Therapeutics Corporation (“UTC”) commenced this action against Defendant Liquidia Technologies, Inc. (“Liquidia”) asserting infringement of U.S. Patent Nos. 9,593,066 (the “’066 patent”), 9,604,901 (the “’901 patent”), and 10,716,793 (the “’793 patent”) by the products that are the subject of Liquidia’s New Drug Application No. 213005 seeking approval by the U.S. Food and Drug Administration (“FDA”) for the manufacture, use, and sale of its proposed product LIQ861 (Yutrepia™);

**WHEREAS**, on January 3, 2022, the Court granted UTC’s stipulation of non-infringement of the ’901 patent based on the Court’s construction of the claim term “contacting the solution comprising treprostinil from step (b) with a base to form a salt of treprostinil,” with UTC preserving all rights to appeal the Court’s construction of that term (D.I. 278);

**WHEREAS**, at trial, UTC asserted infringement of claims 1, 2, 3, 6, 8, and 9 of the ’066 patent and claims 1, 4, 6, 7, and 8 of the ’793 patent against Liquidia, and Liquidia asserted counterclaims of non-infringement and invalidity of those claims;

**WHEREAS**, the Court held a bench trial in the above-captioned action on March 28 to March 31, 2022; and

**WHEREAS**, the Court issued a Trial Opinion setting forth its Findings of Facts and Conclusions of Law on August 31, 2022 (D.I. 433);

**IT IS HEREBY ORDERED AND ADJUDGED:**

1. Judgment is hereby entered in favor of Liquidia and against UTC that claims 1, 2, 3, 6, and 9 of the '066 patent are invalid for the reasons set forth in the Court's Trial Opinion of August 31, 2022 (D.I. 433);

2. Judgment is hereby entered in favor of Liquidia and against UTC that Liquidia's proposed LIQ861 product will not infringe claim 6, 8, and 9 of the '066 patent for the reasons set forth in the Court's Trial Opinion of August 31, 2022 (D.I. 433);

3. Judgment is hereby entered in favor of UTC and against Liquidia that Liquidia's proposed LIQ861 product will induce infringement of claims 1, 4, 6, 7, and 8 of the '793 patent, and that those claims are not invalid, for the reasons set forth in the Court's Trial Opinion of August 31, 2022 (D.I. 433); and

4. Pursuant to 35 U.S.C. § 271(e)(4)(A), it is hereby ordered that the effective date of any final approval by the FDA of Liquidia's New Drug Application No. 213005 shall be a date which is not earlier than the expiration date of the '793 patent.

**IT IS FURTHER ORDERED:**

5. In the event that any party appeals this Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within thirty days after final disposition of any such appeal; and

6. In the event that no party appeals this Final Judgment, any motion for attorneys' fees and/or costs under Fed. R. Civ. P. 54(d) and/or Local Rules 54.1 and/or 54.3, including any motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and

served within thirty days after the expiration of the time for filing a notice of appeal under Federal Rules of Appellate Procedure 3 and 4; and

7. Except as provided herein, all other claims and counterclaims in this action are withdrawn and dismissed with prejudice.

/s/ Richard G. Andrews  
\_\_\_\_\_  
The Honorable Richard G. Andrews  
United States District Judge

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)	
CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-755-RGA-JLH
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

**LIQUIDIA’S BRIEF IN SUPPORT OF MOTION FOR POST JUDGMENT RELIEF  
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 60(B)**

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Dated: December 26, 2023

**TABLE OF CONTENTS**

	<b><u>Page</u></b>
I. NATURE AND STAGE OF THE PROCEEDING.....	1
II. SUMMARY OF THE ARGUMENT .....	2
III. STATEMENT OF FACTS .....	3
IV. ARGUMENT .....	4
A. Applicable Legal Standards. ....	4
B. Relief Is Warranted Under Rule 60(b) Because the Federal Circuit Has Determined that the '793 Patent Claims in this Case Are Invalid. ....	5
C. Enforcing the Judgment Prohibiting FDA Approval Based on the Invalid '793 Patent Claims Would be Inequitable. ....	7
V. CONCLUSION.....	9

## TABLE OF AUTHORITIES

	<u>Page(s)</u>
<b>Cases</b>	
<i>Agostini v. Felton</i> , 521 U.S. 203 (1997).....	4
<i>Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation</i> , 402 U.S. 313, 349-350 (1971) .....	7
<i>Cox v. Horn</i> , 757 F.3d 113 (3d Cir. 2014).....	5
<i>Dragon Intellectual Property, LLC v. Apple, Inc.</i> , Civ. A. No. 13-2058-RGA, 2018 WL 4658208 (D. Del. Sept. 27, 2018) .....	8
<i>ePlus, Inc. v. Lawson Software, Inc.</i> , 789 F.3d 1349 (Fed. Cir. 2015).....	5, 7
<i>Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC</i> , Civ. No. 14-1119-MSG, 2019 WL 3574249 (D. Del. Aug. 6, 2019) .....	4
<i>Horne v. Flores</i> , 557 U.S. 433 (2009).....	4
<i>John Simmons Co. v. Grier Bros. Co.</i> , 258 U.S. 82 (1922).....	6
<i>Laitram Corp. v. NEC Corp.</i> , 163 F.3d 1342 (Fed. Cir. 1998).....	4
<i>Life Technologies, Inc. v. Promega Corp.</i> , 189 F.R.D. 334 (D. Md. 1999).....	8
<i>Liljeberg v. Health Services Acquisition Corp.</i> , 486 U.S. 847 (1988).....	4
<i>In re Linerboard Antitrust Litigation</i> , 361 F. App'x 392 (3d Cir. 2010) .....	4
<i>Markman v. Westview Instruments, Inc.</i> , 517 U.S. 370 (1996).....	4
<i>Mendenhall v. Barber-Greene Co.</i> , 26 F.3d 1573 (Fed. Cir. 1994).....	5, 7, 8
<i>Prism Techs. LLC v. Sprint Spectrum, L.P.</i> , 757 F. App'x 980 (Fed. Cir. 2019) .....	5, 6, 7, 8

## TABLE OF AUTHORITIES

	<u>Page(s)</u>
<i>U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.</i> , 645 F. App’x 1026 (Fed. Cir. 2016) .....	7
<i>United Therapeutics Corp. v. Liquidia Technologies, Inc.</i> , 74 F.4th 1360 (Fed. Cir. 2023) .....	1
<i>XY, LLC v. Trans Ova Genetics, L.C.</i> , 890 F.3d 1282 (Fed. Cir. 2018).....	5, 6, 7
 <b>Statutes</b>	
35 U.S.C. § 103 .....	2
35 U.S.C. § 271(e)(2).....	3
35 U.S.C. §271(e)(4)(A) .....	1, 5
Federal Food, Drug and Cosmetic Act §505(b)(2) .....	3
 <b>Other Authorities</b>	
Fed. R. Civ. P. 60(b) .....	1, 5, 7, 9
Fed. R. Civ. P. Rule 60(b)(5) .....	<i>passim</i>
Fed. R. Civ. P. 60(b)(6).....	4, 6, 8



Pursuant to Federal Rule of Civil Procedure 60(b), Liquidia Technologies, Inc. (“Liquidia”) moves to modify a portion of the September 9, 2022 Final Judgment (D.I. 436) (the “Judgment”) in light of the Federal Circuit’s December 20, 2023 decision affirming the invalidity of U.S. Patent No. 10,716,793 (the “’793 patent”). (Ex. 1 (Fed. Cir. ’793 Patent Decision).) Liquidia asks for relief from the Judgment under 35 U.S.C. §271(e)(4)(A) that is blocking the final approval of Liquidia’s New Drug Application No. 213005 (the “NDA”) until the expiration of the ’793 patent.

## **I. NATURE AND STAGE OF THE PROCEEDING**

In January 2020, Liquidia submitted the NDA to the United States Food and Drug Administration (“FDA”) seeking approval to market its proposed LIQ861 product (“LIQ861”) for the treatment of pulmonary arterial hypertension (“PAH”). Shortly after, United Therapeutics Corporation (“UTC”) filed suit against Liquidia. (D.I. 1.) During pre-trial proceedings, UTC amended its complaint to assert that Liquidia infringed its ’793 patent. (D.I. 16.) After trial, the Court entered Judgment on September 9, 2022, finding that the asserted claims of the ’793 patent were valid and Liquidia induced infringement of those claims. (D.I. 436.) The Court also ordered that, under 35 U.S.C. § 271(e)(4)(A), “the effective date of any final approval by the FDA of Liquidia’s New Drug Application No. 213005 shall be a date which is not earlier than the expiration date of the ’793 patent.” (*Id.*, at ¶ 4.)

Liquidia appealed the Judgment based on the ’793 patent. Subsequently, the Federal Circuit affirmed this Court’s decision regarding the asserted ’793 patent claims on July 24, 2023. *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360 (Fed. Cir. 2023). Currently, Liquidia’s petition for a writ of certiorari by the Supreme Court is due on January 24, 2024.

While the district court proceedings were on-going, Liquidia submitted an *Inter Partes* review (“IPR”) petition regarding the ’793 patent on January 7, 2021. The Patent Trial and

Appeals Board (“PTAB”) instituted review and issued a Final Written Decision (“FWD”) on July 19, 2022, a month before this Court issued Judgment. (Ex. 2 (’793 FWD).) In its FWD, the PTAB found claims 1-8 of the ’793 patent unpatentable as obvious over the prior art under 35 U.S.C. § 103. (*Id.* at 46.) UTC filed a request for rehearing by the PTO’s Precedential Opinion Panel, which was denied on October 26, 2022, but with directions for the PTAB panel to further assess the public availability prior art status of two abstracts. (Ex. 3 (Order to Assess Public Availability).) On February 2, 2023, the PTAB panel denied UTC’s request for rehearing and confirmed that the abstracts were publicly accessible prior art before the ’793 patent’s priority date, although modifying the grounds for that holding. (Ex. 4 (Denial of Rehearing Request, 7–13).) UTC appealed the PTAB panel’s FWD to the Federal Circuit, which affirmed the invalidity ruling in a non-precedential opinion issued on December 20, 2023 (the “Federal Circuit’s ’793 Decision”). (Ex. 1 (Fed. Cir. ’793 Decision).)

## II. SUMMARY OF THE ARGUMENT

In light of the Federal Circuit’s ’793 Decision, Liquidia moves to modify a portion of the Judgment, asking for relief from the infringement ruling and the injunction prohibiting the FDA from granting final approval of Liquidia’s NDA. Relief is appropriate under Rule 60(b)(5) and (b)(6) because, through the Federal Circuit’s affirmance of invalidity, the legal basis for the Court’s Judgment ceases to exist, and it would be inequitable and inconsistent with the public interest to maintain an injunction based on a patent the Federal Circuit affirmed is invalid. By granting relief from Judgment, this Court will ensure that Liquidia is no longer unjustly delayed in bringing LIQ861 to market and to prevent UTC from benefiting from claims that are no longer patentable.

### III. STATEMENT OF FACTS

Liquidia, an innovative biotechnology company, developed a dry inhalation powder formulation of treprostinil, LIQ861, using its proprietary PRINT® technology. LIQ861 has the potential to benefit many PAH patients by not only safely delivering higher doses into the lungs of patients compared to approved conventional inhaled therapies, but also using a low-resistance delivery device, which is easier to use, particularly for patients with PAH. It is also more conveniently administered and contained in a small carrying pouch as opposed to a nebulizer. Liquidia submitted an NDA under §505(b)(2) of the Federal Food, Drug and Cosmetic Act to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of LIQ861.

UTC then filed a patent infringement action under 35 U.S.C. § 271(e)(2) based on its U.S. Patent Nos. 9,593,066 and 9,604,901, later amending its complaint to add infringement allegations of its '793 patent. During pre-trial proceedings, Liquidia filed an IPR petition regarding the '793 patent on January 7, 2021, which the PTAB instituted on August 11, 2021. LIQ861 also received tentative approval from the FDA on November 8, 2021.

After trial, but before this Court entered Judgment, the PTAB held the '793 patent invalid. UTC and Liquidia submitted letters regarding the decision's impact. (D.I. 427; D.I. 428.) The Court still entered Judgment holding that the '793 patent was valid and would be infringed by Liquidia's LIQ861 product. It further ordered the FDA to not approve Liquidia's NDA before the expiration of the '793 patent. (D.I. 436 at ¶ 4.) Since then, the PTAB decision was appealed to the Federal Circuit, where it was affirmed. (Ex. 1 (Fed. Cir. '793 Decision).) Meanwhile, Liquidia has until January 24, 2024 to file its petition for a writ of certiorari regarding the Federal Circuit's affirmance of this Court's decision.

#### IV. ARGUMENT

##### A. Applicable Legal Standards.

“Rule 60(b) authorizes a court to grant relief from a final judgment if ‘applying [the order] prospectively is no longer equitable’ or for ‘any other reason that justifies relief.’” *In re Linerboard Antitrust Litig.*, 361 F. App’x 392, 397 (3d Cir. 2010) (quoting Fed. R. Civ. P. 60(b)(5)). Under Rule 60(b)(5), relief from judgment is warranted if “the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable[.]” Fed. R. Civ. P. 60(b)(5). It allows a party to ask a court to modify or vacate a judgment if a significant change either in facts or in law “renders continued enforcement ‘detrimental to the public interest[.]’” *Horne v. Flores*, 557 U.S. 433, 447 (2009) (quoting *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992)). The Supreme Court has ruled that “it is appropriate to grant a Rule 60(b)(5) motion when the party seeking relief from an injunction or consent decree can show ‘a significant change either in factual conditions or in law.’” *Agostini v. Felton*, 521 U.S. 203, 215 (1997) (quoting *Rufo*, 502 U.S. at 384). The scope of a patent defines a party’s legal rights and is therefore the standard by which a party’s legal rights are judged. *See Laitram Corp. v. NEC Corp.*, 163 F.3d 1342, 1346–47 (Fed. Cir. 1998) (the scope of patent claims “define[s] the scope of the patentee’s rights”); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). Thus, the invalidation of a patent is one such change, eliminating any legal right that party had to exclude others from using the idea.

Additionally, Rule 60(b)(6) is a “catchall provision” that enables courts to vacate judgments whenever such action is appropriate to accomplish justice, though only in extraordinary circumstances. *Forest Lab’ys, LLC v. Sigmapharm Laby’s, LLC*, Civ. No. 14-1119-MSG, 2019 WL 3574249 at \*5 (D. Del. Aug. 6, 2019); *see also Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 863-64 (1988). Extraordinary circumstances are those “where, without such relief,

an extreme and unexpected hardship would occur.” *Cox v. Horn*, 757 F.3d 113, 120 (3d Cir. 2014) (citation omitted). Patent invalidity is one such extraordinary circumstance warranting relief from judgment. *See Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1583 (Fed. Cir. 1994); *Prism Techs. LLC v. Sprint Spectrum, L.P.*, 757 F. App’x 980, 987 (Fed. Cir. 2019).

**B. Relief Is Warranted Under Rule 60(b) Because the Federal Circuit Has Determined that the ’793 Patent Claims in this Case Are Invalid.**

Relief from judgment is warranted because the Federal Circuit has authoritatively determined that the asserted claims in the ’793 patent are invalid and were never patent eligible. (Ex. 1 (Fed. Cir. ’793 Decision).) Indeed, the invalidity of the ’793 patent became final for collateral estoppel purposes once the Federal Circuit affirmed the PTAB’s decision on December 20, 2023. *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018) (finding that the Federal Circuit’s affirmance rendering final a PTAB judgment of invalidity had an immediate preclusive effect on other pending actions involving the patent). Since that date, the legal basis for the Court’s injunction under §271(e)(4)(A) ceased to exist and relief from the Judgement pursuant to Rule 60(b)(5) is warranted. *See ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1354, 1355 (Fed. Cir. 2015) (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *Mendenhall*, 26 F.3d at 1578 (recognizing that upholding an injunction based on a patent would be at odds with the Court’s historical treatment of patents it recently declared invalid). During the parties’ pre-motion meet and confer, UTC indicated it will oppose the instant motion because it intends to seek rehearing by the Federal Circuit. While that is within UTC’s rights, the prospect of panel or *en banc* rehearing is slim because the Federal Circuit issued a unanimous, *non-precedential* opinion that addressed routine issues of prior art status and obviousness. (Ex. 1 (Fed. Cir. ’793 Decision).) Regardless, rehearing

does not negate the finality of the Federal Circuit’s recent decision, as demonstrated by *XY*, nor prohibits the relief currently sought by Liquidia.

This is true even though the Federal Circuit earlier affirmed this Court’s opinion on the ’793 patent. Courts have consistently recognized that a later determination of invalidity justifies setting aside any pending judgment. *See John Simmons Co. v. Grier Bros. Co.*, 258 U.S. 82, 88 (1922) (finding that the district court must apply intervening legal developments affecting the asserted patent’s validity, even if the court of appeals already decided the validity issue the other way); *Medenhall*, 26 F.3d at 1579–80 (holding that “the defense of collateral estoppel based on a final judgment of patent invalidity in another suit can be timely made at any stage of the affected proceedings”) (internal quotation marks and citation omitted).

Alternatively, relief is justified under Rule 60(b)(6) in instances of extraordinary circumstances, such as a ruling of patent invalidity as exemplified in *Prism v. Sprint*. In *Prism*, the Federal Circuit affirmed the district court’s decision that Sprint infringed Prism’s asserted patent claims. But before Sprint had an opportunity to file a petition for certiorari, the Federal Circuit held in a separate case that the asserted claims were invalid. *Prism*, 757 F. App’x at 987. Sprint then sought relief under Rule 60(b)(6), which the district court properly granted given that the asserted claims were invalid. *Id.* at 982–983. The Federal Circuit affirmed, explaining that “courts have long recognized a strong federal patent policy against enforcing an unexecuted judgment of patent liability at least where all of the following circumstances are present: [1] the patent claims underlying that judgment have been held invalid by another decision having sufficient finality for this purpose; [2] proceedings on direct review of the judgment have not yet been completed; and [3] no agreement exists making portions of the judgment final.” *Id.* at 987

(citing *Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 349–350 (1971); *Mendenhall*, 26 F.3d at 1579–1580).

Here, the Federal Circuit's '793 Decision provides sufficient finality of invalidity (*see XY*, 890 F.3d at 1294), and there is no agreement in place rendering portions of this Court's judgment final, satisfying the first and third prongs. As to the completion of review, proceedings in this case have not yet closed. Liquidia's petition for writ of certiorari by the Supreme Court is due January 24, 2024. Finally, Liquidia makes this Rule 60(b) motion within a reasonable time, within days of the Federal Circuit's affirmance of the PTAB decision regarding the invalidity of the '793 patent. Just as in *Prism*, all three prongs are met. Thus, this Court should grant relief from the judgment based on the invalidity of the patent claims.

**C. Enforcing the Judgment Prohibiting FDA Approval Based on the Invalid '793 Patent Claims Would be Inequitable.**

The Federal Circuit's '793 Decision further warrants relief under Rule 60(b)(5) because continuing to enforce a judgment based on an invalid patent is inequitable and detrimental to the public interest. “A patent by its very nature is affected with a public interest” and “[t]he far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.” *Blonder-Tongue*, 402 U.S. at 343 (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). And, as the Federal Circuit has recognized, upholding the injunction would be “anomalous in the extreme in connection with patents this court has just held invalid.” *Mendenhall*, 26 F.3d at 1578; *see also ePlus*, 789 F.3d at 1354–55 (“It is well established that an injunction must be set aside when the legal basis for it has ceased to exist.”); *U.S. Ethernet Innovations, LLC v. Texas Instruments Inc.*, 645 F. App'x 1026, 1029 (Fed. Cir. 2016). The '793 patent has been held invalid and therefore, to continue to uphold an injunction based on a patent

that no longer is enforceable would be *per se* inequitable and detrimental to the public interest. By granting relief from the Judgment, this Court will prevent the manifest injustice that would occur if Liquidia was precluded from obtaining final FDA approval of LIQ861 based on a patent the Federal Circuit has found invalid.

Relief from judgment under Rule 60(b)(5) is further warranted here given the equities of enforcing an invalid patent against one defendant when the patent claims are a nullity as to the rest of the world. *Mendenhall*, 26 F.3d at 1583 (“when the rest of the industry is not impeded by the patents, it seems manifestly unjust to . . . hold[] appellants liable and impair[] their ability to compete.”) Liquidia has successfully challenged the validity of the ’793 patent and succeeded before the PTAB and Federal Circuit. Yet, if relief from Judgment is not granted, Liquidia stands to be the only drug manufacturer that would be precluded from obtaining FDA approval because of the ’793 patent. *See Life Techs., Inc. v. Promega Corp.*, 189 F.R.D. 334, 338 (D. Md. 1999) (remarking that the defendant would be the only competitor unable to practice the unenforceable patent.)

Alternatively, relief from judgment is warranted under Rule 60(b)(6) which gives courts the power to vacate decisions when appropriate to accomplish justice. *Dragon Intell. Prop., LLC v. Apple, Inc.*, Civ. A. No. 13-2058-RGA, 2018 WL 4658208 at \*2 (D. Del. Sept. 27, 2018) (vacating judgment under Rule 60(b)(6) where the Federal Circuit affirmed the PTAB’s finding of invalidity of the claims at issue). This rule is used in extraordinary cases where, without relief, an extreme and unexpected hardship would occur, such as the hardship that would occur to Liquidia as described above if the Judgment was enforced. Moreover, courts have already acknowledged that patent invalidity qualifies as an extraordinary circumstance warranting relief. *See Mendenhall*, 26 F.3d at 1583; *Prism*, 757 F. App’x at 987. Given the patent’s invalidity and the



For the foregoing reasons, Liquidia respectfully requests that the Court grant the relief requested in Liquidia's Rule 60(b) Motion.

Dated: December 26, 2023

# EXHIBIT 1

NOTE: This disposition is nonprecedential.

# United States Court of Appeals for the Federal Circuit

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UNITED THERAPEUTICS CORPORATION,  
*Appellant*

v.

LIQUIDIA TECHNOLOGIES, INC.,  
*Appellee*

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2023-1805

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Appeal from the United States Patent and Trademark  
Office, Patent Trial and Appeal Board in No. IPR2021-  
00406.

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Decided: December 20, 2023

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Before LOURIE, PROST, and REYNA, *Circuit Judges*.

LOURIE, *Circuit Judge*.

United Therapeutics Corporation (“UTC”) appeals from the final written decision of the U.S. Patent and Trademark Office Patent Trial and Appeal Board (“the Board”) in an *inter partes* review (“IPR”) concluding that claims 1–8 of U.S. Patent 10,716,793 (“the ’793 patent”) are unpatentable. *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. IPR2021-00406, 2022 WL 2820717 (P.T.A.B. July 19, 2022) (“*Decision*”). For the following reasons, we *affirm*.

#### BACKGROUND

UTC owns the ’793 patent, which is directed to methods of treating pulmonary hypertension comprising inhalation of treprostinil. Claim 1 is the only independent claim. It reads as follows:

1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

’793 patent at col. 18, ll. 23–31. As relevant here, dependent claims 4, 6, and 7 include additional limitations directed to dry powders. Those claims read as follows:

4. The method of claim 1, wherein the inhalation device is a dry powder inhaler.

UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

3

6. The method of claim 4, wherein the formulation is a powder.

7. The method of claim 6, wherein the powder comprises particles less than 5 micrometers in diameter.

*Id.* at col. 18, ll. 36–37, 40–43.

Liquidia Technologies, Inc. (“Liquidia”) petitioned for IPR of all claims of the ’793 patent, asserting that they would have been obvious over, *inter alia*, U.S. Patent 6,521,212 (“the ’212 patent”), in view of Voswinckel JESC (“JESC”)¹ and Voswinckel JAHA (“JAHA”)² (collectively, “the Voswinckel abstracts”). The ’212 patent, an unrelated patent owned by UTC, is directed to methods of delivering benzindene prostaglandins, such as treprostinil sodium, to patients via inhalation to treat pulmonary hypertension. *See* ’212 patent at Abstract, J.A. 1207. JESC is an abstract that describes a study in which patients inhaled solutions of treprostinil in concentrations of 16, 32, 48, and 64 µg/mL via a nebulizer. *See* J.A. 1240. JAHA is an abstract that describes a study in which patients inhaled solutions of treprostinil sodium via a nebulizer in 3 single breaths. *See id.* at 1243.

Before the Board, UTC challenged the prior art status of the Voswinckel abstracts, arguing that Liquidia had failed to adequately show that those references qualified as “printed publications” under pre-AIA 35 U.S.C. § 102(b).

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¹ R. Voswinckel et al., *Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension*, 25 EUROPEAN HEART J. 22 (2004), J.A. 1234–1240.

² Robert Voswinckel et al., *Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension*, in Abstracts from the 2004 Scientific Sessions of the American Heart Association, 110 CIRCULATION III-295 (Oct. 26, 2004), J.A. 1241–43.

*Decision* at \*3. Specifically, UTC argued that, because in its petition Liquidia relied on those abstracts having been stored in libraries, it was required to establish that the abstracts would have both been available at the library and sufficiently indexed or categorized by priority date. *Id.* at \*4. The Board observed, however, that Liquidia had not relied solely on the availability of those references in libraries to establish their prior art status. *Id.* Rather, Liquidia had also asserted that each abstract had been presented at a public conference and that they were both cited in other documents dating from before the priority date of the '793 patent. *Id.* On the second of these two theories, the Board concluded that Liquidia had shown by a preponderance of the evidence that each of the Voswinckel abstracts was prior art because it had been cited in a “research aid,” *i.e.*, a publicly accessible article that provided a “sufficiently definite roadmap leading to” the abstract. *Id.* at \*5 (quoting *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016)).

Having found the Voswinckel abstracts to be prior art, the Board concluded that a person of ordinary skill in the art would have been motivated to combine those abstracts with the '212 patent to arrive at the claimed invention. *See id.* at \*5–9. This, the Board found, was true despite UTC's evidence of objective indicia of nonobviousness, such as unexpected results, copying, and long-felt and unmet need. *Id.* at \*9–13. Accordingly, the Board found all claims of the '793 patent unpatentable as obvious. *See id.* at \*15.

UTC requested rehearing of the Board's decision, and included a request for rehearing by the U.S. Patent and Trademark Office's Precedential Opinion Panel (“the Panel”) on the issue of whether or not the Voswinckel abstracts were prior art. *See Liquidia Tech., Inc. v. United Therapeutics Corp.*, IPR2021-00406, Paper 81 (Oct. 26, 2022) at 2, J.A. 885. The Panel denied UTC's request but determined that the Board had failed to consider whether the “research aids” in which the abstracts were cited were

UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

5

themselves available prior to the critical date of the '793 patent, *i.e.*, May 15, 2005. *Id.* It also determined that the Board had not adequately addressed whether the Voswinckel abstracts “were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library.” *Id.* Accordingly, the Panel directed the Board to, in its consideration on rehearing, “clearly identify whether the [Voswinckel abstracts] qualify as prior art.” *Id.* at 3, J.A. 886.

In its decision on rehearing, the Board maintained that the Voswinckel abstracts were prior art. *See Liquidia Tech., Inc. v. United Therapeutics Corp.*, IPR2021-00406, Paper 82 (Feb. 2, 2023) (“*Rehearing Decision*”), J.A. 50–67. Conceding that it had overlooked the fact that the research aids did not pre-date May 15, 2005, *see id.* at 5–7, J.A. 54–56, the Board nevertheless found that Liquidia had adequately shown that the abstracts had been publicly distributed at conferences prior to that date, *id.* at 7–12, J.A. 56–61. Specifically, the Board concluded that JESC was distributed at the European Society of Cardiology Congress that was held from August 28, 2004, to September 1, 2004, in Munich, Germany, and that JAHA was distributed at the American Heart Association’s Scientific Sessions that occurred from November 7, 2004, to November 10, 2004, in New Orleans, Louisiana. *Id.*; *see* J.A. 1241. Both parties’ experts agreed that a person of ordinary skill in the art would have been one of over 20,000 attendees at each of those conferences and that an “abstract book” from which each of the abstracts was excerpted would have been provided to all attendees. *Rehearing Decision* at 10, 12, J.A. 59, 61. Accordingly, the Board maintained that the abstracts were prior art and denied UTC’s rehearing request.

UTC timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A) and 35 U.S.C. § 141(c).

## DISCUSSION

We review the Board’s legal determinations *de novo*, *In re Elsner*, 381 F.3d 1125, 1127 (Fed. Cir. 2004), and its factual findings for substantial evidence, *In re Gartside*, 203 F.3d 1305, 1316 (Fed. Cir. 2000). A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding. *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). Moreover, we review the Board’s determination whether, under the Board’s own regulations, a party exceeded the scope of a proper reply for abuse of discretion. *Axonics, Inc. v. Medtronic, Inc.*, 75 F.4th 1374, 1380 (Fed. Cir. 2023).

UTC raises three challenges on appeal. First, it argues that the Board erred in determining that the Voswinckel abstracts are prior art. Second, it argues that, even if those abstracts are prior art, the Board erred in finding that the claimed dose would have been obvious over the ’212 patent in combination with the Voswinckel abstracts. And finally, it argues that the Board legally erred in its treatment of dependent claims 4, 6, and 7, and that its obviousness determination as to those claims was not supported by substantial evidence. We address each argument in turn.

### I

UTC contends that the Board’s prior art analysis as to the Voswinckel abstracts suffered from two errors. First, it argues that the Board’s analysis improperly exceeded the prior art theories set forth in Liquidia’s petition. Second, it argues that the Board’s determination that the abstracts were publicly accessible as of the critical date was not supported by substantial evidence.

### A

By statute, the scope of an IPR is limited to the grounds set forth in the initial petition. 35 U.S.C. § 312(a)(3); *see SAS Inst. Inc., v. Iancu*, 138 S. Ct. 1348, 1357 (“[T]he statute tells us that the petitioner’s contentions, not the



UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

7

Director’s discretion, define the scope of the litigation all the way from institution through to conclusion.”). It is therefore improper for the Board to deviate from the grounds in the petition and raise its own theories of unpatentability. *Sirona Dental Sys. GmbH v. Institut Straumann AG*, 892 F.3d 1349, 1356 (Fed. Cir. 2018). UTC argues that the Board violated this principle when it concluded that the Voswinckel abstracts were prior art based on an “abstract book” theory. In UTC’s view, this theory was not advanced by Liquidia until its Reply before the Board, and that it was therefore untimely. *See* Appellant’s Br. at 33. We disagree.

As the Board recognized, Liquidia’s IPR petition asserted that each of the Voswinckel abstracts was publicly presented or published at least one year before the priority date of the ’793 patent, making each of them printed publications within the meaning of § 102(b). *See Decision* at \*4; *see also* Petition at 22, 24, J.A. 133, 135. UTC first challenged the sufficiency of those grounds in its post-institution Patent Owner Response. *See* Patent Owner Response at 11–18, J.A. 372–79. Thereafter, in its Reply, Liquidia asserted, with additional evidence, that both Voswinckel abstracts were publicly presented and sufficiently disseminated at conferences prior to the critical date such that they qualified as printed publications. *See* J.A. 471, 474–75.

The Board found that Liquidia’s arguments and evidence raised in its Reply were not untimely as they were made in direct response to UTC’s attack on the prior art status of the abstracts first raised in its post-institution Patent Owner Response. *Decision* at \*4, J.A. 10. This conclusion was not an abuse of the Board’s discretion. *See Anacor Pharms., Inc. v. Iancu*, 889 F.3d 1372, 1380–82 (Fed. Cir. 2018) (explaining that the petitioner “may introduce new evidence after the petition stage if the evidence is a legitimate reply to evidence introduced by the patent owner”); *see also Axonics*, 75 F.4th at 1380 (explaining that a

petitioner’s entitlement to respond to new arguments made in a patent owner response is consistent with SAS). As the Board observed, Liquidia’s arguments were not inconsistent with, and therefore not new over, the grounds raised in its IPR petition—that the Voswinckel abstracts were publicly accessible prior to the critical date. *Ericsson Inc. v. Intell. Ventures I LLC*, 901 F.3d 1374, 1380 (Fed. Cir. 2018) (“[T]he Board has discretion to determine whether a petition for *inter partes* review identified the specific evidence relied on in a reply and when a reply contention crosses the line from the responsive to the new.”). Accordingly, we conclude that the Board did not abuse its discretion in considering the arguments and evidence raised in Liquidia’s Reply.

B

UTC next argues that, even if timely, the Board erred in finding that the Voswinckel abstracts were publicly accessible because its “abstract book” theory was entirely “hypothetical” and supported only by “conclusory expert testimony.” Appellant’s Br. at 37. In its view, the Board’s theory would have been adequately supported only if Liquidia had provided “evidence of *actual* existence or dissemination” of the books. *Id.* (emphasis added). But that is not the proper standard.

Public accessibility is the “touchstone in determining whether a reference constitutes a ‘printed publication.’” *Blue Calypso*, 815 F.3d at 1348 (quoting *In re Hall*, 781 F.3d 897, 898–99 (Fed. Cir. 1986)). “Our cases have consistently held that the standard for public accessibility is whether a person of ordinary skill in the art *could*, after exercising reasonable diligence, access a reference.” *Samsung Elecs. Co. v. Infobridge Pte. Ltd.*, 929 F.3d 1363, 1374 (Fed. Cir. 2019). Once accessibility is proved, “there is no requirement to show that particular members of the public *actually received* the information.” *Jazz Pharms., Inc. v. Amneal Pharms., LLC*, 895 F.3d 1347, 1356 (Fed. Cir.

UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

9

2018) (quoting *Constant v. Adv. Micro-Devices, Inc.*, 848 F.2d 1560, 1569 (Fed. Cir. 1988)) (emphasis added). Contrary to UTC's position then, Liquidia had no obligation to produce, for example, a declarant testifying to having received the abstract books in which the Voswinckel abstracts appeared, let alone the abstract books themselves.

We find that the Board's conclusion that the Voswinckel abstracts were sufficiently disseminated such that each constituted a printed publication was supported by substantial evidence. Specifically, the Board determined that the two 2004 conferences at which the abstracts were presented were attended by over 20,000 attendees. *Rehearing Decision* at 7–12, J.A. 58–61. And both Liquidia's and UTC's experts testified that every attendee of either conference would have received a copy of the abstract book in which each of the Voswinckel abstracts appeared. *See id.* Further still, the Board found that neither abstract book would have been disseminated with any expectation of privacy, given that the conference attendees included scientists, physicians, and nurses, *as well as* journalists. *See id.* at 59. Substantial evidence therefore supports the Board's conclusion that the Voswinckel abstracts qualify as prior art.

## II

UTC's next challenges pertain to the Board's obviousness analysis as to independent claim 1.

### A

Claim 1 requires the inhalation of a therapeutically effective single event dose of 15 micrograms to 90 micrograms of treprostinil or a therapeutically acceptable salt thereof. '793 patent at col. 18, ll. 28–30. The Board concluded that, although no reference explicitly taught this dose, the person of ordinary skill in the art would have understood the solutions in JESC to have delivered an

amount of treprostinil within the claimed range. *Decision* at \*6–7. That finding was supported by substantial evidence.

JESC discloses the administration of treprostinil solution via a nebulizer to patients in concentrations of 16, 32, 48, and 64 µg/mL. J.A. 1240. As the Board recognized, JESC does not disclose the volume of solution administered, which is necessary to calculate the amount (in µg) of treprostinil administered. *Decision* at \*6. Accordingly, the Board looked to the declarations of Liquidia’s two experts, each of which testified that, at the time of the invention, nebulizers delivered at least 1 mL and up to 5 mL of solution. *Id.* (citing J.A. 1054, 1166). Based on those delivery volumes, the Board concluded that the amounts of treprostinil delivered in JESC would have been from 16–80, 32–160, 48–240, or 64–320 µg, each of which has at least one endpoint that falls within the claimed range of 15–90 µg. *Id.*

UTC argues that the Board’s conclusion was error because the experts’ testimony related only to *fill* volume, not volume actually delivered. Appellant’s Br. at 43. Because no nebulizer can be 100% efficient, UTC argues it was error to rely on the experts’ testimony without accounting for other factors, such as patients’ breathing volume and patterns, and individual nebulizer characteristics (*e.g.*, residual volume, nebulization rate, etc.). *Id.* But the Board considered, and rejected, those same arguments. Specifically, it concluded that, “[t]o the extent that something less than the entire fill volume was delivered to the patient, . . . the preponderance of the evidence still supports actual delivered solution volume being at least one milliliter.” *Decision* at \*7. And, to be sure, UTC’s own expert testified that, in 2006, he had not administered treprostinil via a nebulizer that utilized less than one milliliter of drug solution. *Id.* (citing J.A. 3185).

UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

11

Accordingly, the Board’s finding that the combination of the ’212 patent, JESC, and JAHA would have rendered obvious claim 1 was supported by substantial evidence.

### B

UTC further challenges the Board’s consideration of its evidence of objective indicia of nonobviousness, arguing that the Board “clearly erred” by concluding that UTC had failed to even allege that the invention demonstrated unexpected results over the ’212 patent, JESC, and JAHA. Appellant’s Br. at 49–50 (citing *Decision* at \*10). This argument, only a single paragraph in UTC’s opening brief, borders on waiver. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006). But even if given due consideration, we conclude that the Board’s determination was supported by substantial evidence.

Before the Board, UTC only provided evidence that the claimed compositions exhibited unexpected results over inhaled iloprost, intravenous epoprostenol, and intravenous treprostinil. *See Decision* at \*10. But, as the Board recognized, the claims require inhaled treprostinil, which is taught by each of the ’212 patent, JESC, and JAHA, making those references the closest prior art. And the only argument made by UTC that the claimed invention was unexpected over those references was a conclusory statement that “the ability to administer treprostinil at high doses in only 1–3 breaths and with fewer side effects was unexpected.” J.A. 585. With no other evidence to consider, we see no error in the Board’s conclusion that UTC failed to satisfy its burden in establishing unexpected results.

### III

Finally, we turn to UTC’s challenge to the Board’s treatment of dependent claims 4, 6, and 7, which are directed to the inhalation of dry powder formulations of treprostinil. UTC argues that the Board failed to consider each claim as a separate invention and that none of the ’212

patent, JESC, or JAHA discloses any dry powder dosages. Specifically, it argues that the Board failed to explain why a person of ordinary skill in the art would “reasonably expect to succeed in preparing a therapeutically effective *dry powder* formulation” using concentrations prepared only for solutions. Appellant’s Br. at 55.

But, as Liquidia explains, UTC never raised this particular argument before the Board. Instead, it argued that claims 4, 6, and 7 were not obvious “because the prior art lacks disclosure of a single event dose of 15–90 µg delivered in 1–3 breaths, *regardless of the form of administration* (liquid or powder).” Patent Owner Response at 41, J.A. 401 (emphases added). We therefore find UTC’s argument forfeited. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 582 F.3d 1288, 1296 (Fed. Cir. 2009) (explaining that this court may decline to consider an argument “[i]f a party fail[ed] to raise [that] argument before the trial court, or present[ed] only a skeletal or undeveloped argument to the trial court.”).

In any event, the Board’s conclusion that dependent claims 4, 6, and 7 were obvious was supported by substantial evidence. Namely, as the Board observed, the ’212 patent, which is also owned by UTC, discloses the use of an “inhaler,” and that “solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention.” ’212 patent at col. 5, ll. 30, 37–39, J.A. 1228. It also teaches that such formulations have particle sizes of preferably “less than 5 micrometers in diameter.” *Id.* at col. 5, ll. 39–41, J.A. 1228. The Board relied not only on these disclosures, but also on the un rebutted testimony of Liquidia’s expert that a person of ordinary skill in the art would have had a reasonable expectation of success in arriving at the claimed dry powder formulation based on the combined teachings of the ’212 patent, JESC, and JAHA. *Decision* at \*14.

UNITED THERAPEUTICS CORPORATION v.  
LIQUIDIA TECHNOLOGIES, INC.

13

#### CONCLUSION

We have considered UTC's remaining arguments and find them unpersuasive. For the reasons provided above, we *affirm* the Board's unpatentability determination.

**AFFIRMED**

# EXHIBIT 2



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Paper 78  
Entered: July 19, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,  
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,  
Patent Owner.

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IPR2021-00406  
Patent 10,716,793 B2

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Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER,  
and DAVID COTTA, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

JUDGMENT  
Final Written Decision  
Determining All Challenged Claims Unpatentable  
35 U.S.C. § 318(a)

IPR2021-00406  
Patent 10,716,793 B2

## INTRODUCTION

### *A. Background*

Liquidia Technologies, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, “the ’793 patent”). United Therapeutics Corporation (“Patent Owner”) filed a Preliminary Response. Paper 13 (“Prelim. Resp.”).

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the ’793 patent on all grounds set forth in the Petition. Paper 18 (“Inst. Dec.”). After institution of trial, Patent Owner filed a Response (Paper 29, “PO Resp.”), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents’ Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which has been entered into the record. Paper 77 (“Tr.”).

We have jurisdiction under 35 U.S.C. § 6. This is a Final Written Decision under 35 U.S.C. § 318(a) as to the patentability of the challenged claims of the ’793 patent. For the reasons discussed below, we determine Petitioner has established by a preponderance of the evidence that each of claims 1–8 of the ’793 patent is unpatentable.

### *B. Related Matters*

The parties identify *United Therapeutics Corporation v. Liquidia Technologies, Inc.*, 1:20-cv-00755-RGA (D. Del.) (“the District Court proceeding”), as a related matter. Pet. 1; Paper 3, 1.

IPR2021-00406  
Patent 10,716,793 B2

*C. The Asserted Grounds of Unpatentability*

Petitioner contends that claims 1–8 of the ’793 patent are unpatentable based on the following grounds (Pet. 30–68):<sup>1</sup>

Claim(s) Challenged	35 U.S.C. § <sup>2</sup>	Reference(s)/Basis
1–8	103(a)	’212 patent, <sup>3</sup> Voswinckel JESC, <sup>4</sup> Voswinckel JAHA <sup>5</sup>
1–8	103(a)	’212 patent, Voswinckel JESC
1	102(a)	Ghofrani <sup>6</sup>
1, 3, 8	103(a)	Voswinckel JAHA, Ghofrani
1, 3	102(a)	Voswinckel 2006 <sup>7</sup>

<sup>1</sup> Petitioner also relies on declarations from Nicholas Hill, M.D., and Igor Gonda, Ph.D. Exs. 1002, 1004, 1106, 1107.

<sup>2</sup> The ’793 patent claims a priority date of May 15, 2006, and Petitioner “assumes the relevant priority date . . . is May 15, 2006.” Pet. 12; Ex. 1001, code (60). Accordingly, patentability is governed by the versions of 35 U.S.C. §§ 102 and 103 preceding the amendments in the Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011).

<sup>3</sup> US 6,521,212 B1, issued Feb. 18, 2003 (Ex. 1006) (alleged to be prior art under 35 U.S.C. §§ 102(a), (b), (e)).

<sup>4</sup> Voswinckel, R., et al., *Inhaled treprostinil is a potent pulmonary vasodilator in severe pulmonary hypertension*, 25 EUROPEAN HEART J. 22 (2004) (Ex. 1007) (alleged to be prior art under 35 U.S.C. § 102(b)).

<sup>5</sup> Robert Voswinckel, et al., *Inhaled Treprostinil Sodium (TRE) For the Treatment of Pulmonary Hypertension*, in Abstracts from the 2004 Scientific Sessions of the American Heart Association, 110 CIRCULATION III-295 (Oct. 26, 2004) (Ex. 1008) (alleged to be prior art under 35 U.S.C. § 102(b)).

<sup>6</sup> Hossein Ardeschir Ghofrani, et al., *Neue Therapieoptionen in der Behandlung der pulmonalerteriellen Hypertonie*, 30 HERZ 296–302 (June 2005) (Ex. 1010) (alleged to be prior art under 35 U.S.C. § 102(a)). We rely on the English translation that follows the German original article as part of Ex. 1010.

<sup>7</sup> Robert Voswinckel, et al., *Inhaled Treprostinil for Treatment of Chronic Pulmonary Arterial Hypertension*, 144 ANNALS OF INTERNAL MEDICINE

IPR2021-00406  
 Patent 10,716,793 B2

Claim(s) Challenged	35 U.S.C. §²	Reference(s)/Basis
2, 4–8	103(a)	Voswinckel 2006, '212 patent

#### *D. The '793 Patent*

The '793 patent, titled “Treprostinil Administration by Inhalation,” issued on July 21, 2020. Ex. 1001, codes (45), (54). The patent “relates to methods and kits for therapeutic treatment and, more particularly, to therapeutic methods involving administering treprostinil using a metered dose inhaler and related kits.” *Id.* at 1:20–23.

Treprostinil “is a prostacyclin analogue” that may be used to treat pulmonary hypertension. *Id.* at 5:37–41. According to the '793 patent, it was previously known to administer treprostinil by intravenous, subcutaneous, or inhalation routes to treat any of several conditions, including pulmonary hypertension. *Id.* at 5:42–58.

The '793 patent relates to the administration of treprostinil in high concentrations over a short inhalation time. *Id.* at 16:61–63, 17:44–46. This method of administration is described as reducing pulmonary vascular resistance and pulmonary artery pressure, as well as increasing cardiac output. *Id.* at 16:32–42, Fig. 10.

#### *E. Illustrative Claim*

Claims 1–8 of the '793 patent are challenged. Claim 1 is independent and illustrative; it recites:

1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a

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149–50 (January 2006) (Ex. 1009) (alleged to be prior art under 35 U.S.C. § 102(a)).

IPR2021-00406

Patent 10,716,793 B2

formulation comprising treprostinil or a pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

Ex. 1001, 18:23–31.

## ANALYSIS

### *A. Claim Construction*

In an *inter partes* review, we construe a claim in an unexpired patent “in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent.” 37 C.F.R. § 42.100(b) (2020). “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). “Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.” *Id.*

Neither party presents any terms for construction. Pet. 12–13 (“Petitioner does not believe construction of any claim term is required”); PO Resp. 7 (not proposing construction of any terms). Accordingly, we determine that no express construction of any claim term is necessary in order to decide whether to institute trial. *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (citing *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)

IPR2021-00406  
Patent 10,716,793 B2

(“[O]nly those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy.”)).

*B. Asserted Obviousness over '212 Patent, Voswinckel JESC, and Voswinckel JAHA*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–46. Patent Owner argues that Petitioner fails to show that Voswinckel JESC and Voswinckel JAHA are prior art to the '793 patent. PO Resp. 11–18. Patent Owner also argues that Petitioner fails to show that this combination of references teaches or suggest all the limitations of any of the challenged claims. PO Resp. 18–22, 38–40. In addition, Patent Owner also argues that Petitioner fails to show that a person of ordinary skill in the art would have had a reason to combine the teachings of these references. *Id.* at 23–38.

*1. '212 Patent*

The '212 patent teaches “[a] method of delivering benzindene prostaglandins to a patient by inhalation.” Ex. 1006, code (57). In particular, the '212 patent teaches the use of “[a] benzindene prostaglandin known as UT-15,” which “has unexpectedly superior results when administered by inhalation compared to parenterally administered UT-15 in sheep with induced pulmonary hypertension.” *Id.* There is evidence in the present record that “UT-15” was also known as “Remodulin” or “treprostinil sodium.” Ex. 1035, 582. According to the '212 patent, the UT-15 may be delivered either as droplets formed “from a solution or liquid containing the active ingredient(s)” via a nebulizer, or as a solid-phase powder via an inhaler. Ex. 1006, 5:30–41.

IPR2021-00406

Patent 10,716,793 B2

According to the '212 patent, this method may be used to “treat[] pulmonary hypertension in a mammal.” *Id.* at 14:9–12. Moreover, the '212 patent teaches “medical use” of its method in a “human.” *Id.* at 7:4–5. The necessary dose to achieve “a particular therapeutic purpose will, of course, depend upon the specific circumstances of the patient being treated and the magnitude of the effect desired by the patient’s doctor. Titration to effect may be used to determine proper dosage.” *Id.* at 6:66–7:3. “[A]erosolized UT-15 has a greater potency as compared to intravascularly administered UT-15,” so the '212 patent teaches delivering “only a fraction (10–50%) of the dosage delivered intravascularly” when using its inhalation delivery method. *Id.* at 8:8–12. Even at “high doses,” however, the '212 patent teaches a lack of “significant non-lung effects, i.e., heart rate, cardiac output.” *Id.* at 10:51–54.

## 2. *Voswinckel JESC*

Voswinckel JESC discusses a study to investigate “the acute hemodynamic response to inhaled treprostinil.” Ex. 1007, 7. Of the 29 patients in the study, eight were administered a placebo, groups of six patients each were administered 16, 32, and 48 µg/mL solutions of treprostinil, and three patients were administered a solution containing 64 µg/mL of treprostinil. *Id.* Each administration used an “OptiNeb ultrasound nebulizer, [made by] Nebu-Tec, Germany” for six minutes. *Id.* For each patient, various measurements were taken before administration of the treprostinil and at 0, 15, 30, 60, 90, 120, 150, and 180 minutes after administration. *Id.* According to Voswinckel JESC, “[t]reprostinil inhalation results in a significant long-lasting pulmonary vasodilatation,”

IPR2021-00406

Patent 10,716,793 B2

and, “at a concentration of 16 µg/mL, near maximal pulmonary vasodilatation is achieved without adverse effects.” *Id.*

3. *Voswinckel JAHA*

Voswinckel JAHA discusses a study of 17 patients with “severe pulmonary hypertension” who received treprostinil inhalations. Ex. 1008, 3. These inhalations each involved “3 single breaths” using a “pulsed OptiNeb® ultrasound nebulizer” and a “600 µg/mL” treprostinil solution. *Id.* In addition, “[t]wo patients with idiopathic PAH received compassionate treatment with 4 inhalations of TRE per day after the acute test” and were “treated for more than 3 months.” *Id.* According to Voswinckel JAHA, “inhalation resulted in a sustained, highly pulmonary selective vasodilatation over 120 minutes,” showing “strong pulmonary selective vasodilatory efficacy with a long duration of effect following single acute dosing,” and “[t]olerability is excellent even at high drug concentrations and short inhalation times (3 breaths).” *Id.*

4. *Prior-Art Status of Voswinckel JESC and Voswinckel JAHA*

In arguing that claims 1–8 would have been obvious, Petitioner relies on Voswinckel JESC and Voswinckel JAHA, but Patent Owner argues that Petitioner fails to show sufficiently that either of these references qualifies as a “printed publication.” PO Resp. 11–18.

Only “prior art consisting of patents or printed publications” may form “the basis of” an *inter partes* review. 35 U.S.C. § 311(b). Neither Voswinckel JESC nor Voswinckel JAHA is a patent, so Petitioner may not rely on these references unless they are “printed publications.” *Id.* Public accessibility is the “touchstone in determining whether a reference constitutes a printed publication,” and a reference is considered publicly



IPR2021-00406  
Patent 10,716,793 B2

accessible only if it was “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it.” *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1350 (Fed. Cir. 2008) (quoting *SRI Int’l, Inc. v. Internet Sec. Sys. Inc.*, 511 F.3d 1186, 1194 (Fed. Cir. 2008); *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986)).

Patent Owner argues that, because Petitioner relies on Voswinckel JESC and Voswinckel JAHA having been “stored in libraries, public accessibility requires that the reference be both available at the library and sufficiently indexed or catalogued by the priority date.” PO Resp. 12 (citing *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1348 (Fed. Cir. 2016); *In re Klopfenstein*, 380 F.3d 1345, 1349 (Fed. Cir. 2004)). According to Patent Owner, Petitioner fails to show sufficiently either of these requirements. *Id.* at 12–18.

But Petitioner does not rely solely on availability in libraries to show the prior-art status of Voswinckel JESC and Voswinckel JAHA. Instead, Petitioner also argues that “Voswinckel JESC is an abstract presented at the European Society of Cardiology (JESC) Congress,” that Voswinckel JAHA “was publicly presented at the 2004 Scientific Sessions of the American Heart Association,” and that both references were cited in other documents dating from before the priority date of the ’793 patent whose public accessibility is not at issue. Pet. 22; Reply 3–4, 6–8.

Patent Owner objects that Petitioner’s public-presentation and citation-in-other-references arguments are untimely because they should have been, but were not, presented in the Petition. Sur-Reply 2–3. We disagree. First, the argument that Voswinckel JESC was presented publicly

IPR2021-00406  
Patent 10,716,793 B2

appears in the Petition. Pet. 22. Second, although other of Petitioner’s arguments appear for the first time in the Reply, they are not untimely. Reply 3–4, 6–8.

Petitioner is permitted a “limited opportunit[y]” to present new evidence in or with its Reply, as long as that new evidence is “responsive to the prior briefing” and does not constitute “changing theories after filing [the] petition.” *Hulu, LLC v. Sound View Innovations, LLC*, IPR2018-01039, Paper 29, at 14–15 (PTAB Dec. 20, 2019) (precedential). Here, both of the arguments that Patent Owner alleges are new—the argument that Voswinckel JESC and Voswinckel JAHA were presented publicly and the argument that these references were cited in other publicly available references—respond to Patent Owner’s argument in the Patent Owner Response that Voswinckel JESC and Voswinckel JAHA were not publicly accessible. PO Resp. 11–18. The argument that Voswinckel JESC was publicly presented is not a change in theory from the Petition, because Petitioner presented this argument in the Petition. Pet. 22. As to both Voswinckel JESC and Voswinckel JAHA, Petitioner’s Reply evidence showing citation to the references in other publicly accessible documents is merely additional evidence supporting Petitioner’s original theory that a person of ordinary skill in the art could have located the references. Accordingly, we find that the following arguments made by Petitioner are not untimely: (1) that Voswinckel JESC was presented publicly, (2) that Voswinckel JESC was referenced in a publicly accessible document, and (3) that Voswinckel JAHA was referenced in a publicly accessible document.

Given the evidence supporting Petitioner’s timely arguments, we are persuaded that Petitioner has shown by a preponderance of the evidence that

IPR2021-00406

Patent 10,716,793 B2

Voswinckel JESC and Voswinckel JAHA were publicly accessible. “[T]he presence of a ‘research aid’ can . . . establish public accessibility” of a reference if that research aid “provide[s] a skilled artisan with a sufficiently definite roadmap leading to” the reference by “provid[ing] enough details [to] determine that an interested party is reasonably certain to arrive at the destination: the potentially invalidating reference.” *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1350 (Fed. Cir. 2016).

Here, Petitioner directs us to research aids for finding both Voswinckel JESC and Voswinckel JAHA: a “June 2005 Ghofrani article in the journal *Herz*” for the former, and “a March 2005 article authored by Roxana Sulica et al. in the *Expert Review of Cardiovascular Therapy*” for the latter. Reply 3, 7 (citing Ex. 1010, 298, 301; Ex. 1104, 359). The Ghofrani article cites Voswinckel JESC as providing a solution to patients experiencing “pain at the injection site” by replacing injected treprostinil for “pulmonary arterial hypertension” with “*inhaled* treprostinil.” Ex. 1010, 298 (citing reference 6), 301 (defining reference 6 as Voswinckel JESC). The Ghofrani article also discusses the study reported in Voswinckel JESC, summarizing both the “major reduction in pulmonary selective pressure and resistance” and the lack of “adverse effects” described in Voswinckel JESC. *Id.* The Sulica article cites to Voswinckel JAHA, explaining that the reference reports that “inhaled treprostinil demonstrated substantial pulmonary vasodilatory efficacy in acute administration, as well as symptomatic and functional benefit in chronic use in a small number of PAH patients.” Ex. 1104, 351, 359. Thus, both the Ghofrani article and the Sulica article provide roadmaps directing a person of ordinary skill in the art looking for successful studies discussing the use of inhaled treprostinil in

IPR2021-00406

Patent 10,716,793 B2

pulmonary arterial hypertension straight to Voswinckel JESC or Voswinckel JAHA. Because these articles provide these roadmaps, they are “research aid[s]” that “establish [the] public accessibility” of Voswinckel JESC and Voswinckel JAHA. *Blue Calypso*, 815 F.3d at 1350.

### 5. *Analysis*

Petitioner argues that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of claims 1–8 and that a person of ordinary skill in the art would have had a reason to combine the teachings of these references with a reasonable expectation of success. Pet. 30–46. Patent Owner argues that this combination of references fails to teach or suggest delivering a dose of treprostinil within the dose range of the challenged claims in a single dosing event of one to three breaths. Prelim. Resp. 42–55.

#### a. Claim 1

*(1) “A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof”*

Claim 1 recites “[a] method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a pharmaceutically acceptable salt thereof.” Ex. 1001, 18:23–27. Petitioner argues that the ’212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation. Pet. 35–37. Patent Owner does not dispute this argument. PO Resp. 10–40.

IPR2021-00406

Patent 10,716,793 B2

The '212 patent teaches treating pulmonary hypertension via inhalation of a benzindene prostaglandin called UT-15, which was also known as “treprostinil sodium.” Ex. 1006, code (57) (identifying “benzindene prostaglandin” as “UT-15”), 2:66–3:5 (“This invention relates to . . . a method of treating pulmonary hypertension by administering an effective amount of a benzindene prostaglandin to a mammal in need thereof by inhalation.”); Ex. 1035, 582 (“UT-15” also known as “treprostinil sodium”). Voswinckel JAHA teaches treating “patients with severe pulmonary hypertension” with “Inhaled Treprostinil Sodium (TRE)” with “3 single breaths” of “TRE solution 600 µg/ml,” resulting in “strong pulmonary selective vasodilatory efficacy with a long duration of effect following single acute dosing.” Ex. 1008, 3. Voswinckel JESC describes “the acute hemodynamic response to inhaled treprostinil” following the administration to patients of nebulized treprostinil solution in concentrations of 16, 32, 48, and 64 µg/ml for six minutes, resulting in “significant long-lasting pulmonary vasodilatation” without “adverse effects.” Ex. 1007, 7.

Accordingly, Petitioner has shown by a preponderance of the evidence that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this portion of claim 1.

*(2) “With an inhalation device”*

Next, claim 1 recites “with an inhalation device.” Ex. 1001, 18:27–28. Petitioner argues that the '212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation. Pet. 37. Patent Owner does not dispute this argument. PO Resp. 10–40. The '212 patent teaches the use in its inhalation method of “a nebulizer, inhaler, atomizer or aerosolizer” to “form[] droplets from a solution or liquid containing the

IPR2021-00406  
Patent 10,716,793 B2

active ingredient(s).” Ex. 1006, 5:30–32. Both Voswinckel JESC and Voswinckel JAHA teach the use of a “nebulizer” in their inhalation methods. Ex. 1007, 7 (“OptiNeb ultrasound nebulizer”); Ex. 1008, 3 (“the pulsed OptiNeb® ultrasound nebulizer”). Dr. Hill testifies that a person of ordinary skill in the art would have understood “that nebulizers and inhalers are inhalation devices.” Ex. 1002 ¶ 94. Accordingly, Petitioner has shown by a preponderance of the evidence that the ’212 patent, Voswinckel JESC, and Voswinckel JAHA each teach or suggest this limitation of claim 1.

*(3) “Wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof”*

Claim 1 recites “wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof.” Ex. 1001, 18:28–30. Petitioner argues that the combination of the ’212 patent and Voswinckel JESC teaches or suggests this limitation. Pet. 37–40. Patent Owner disagrees. PO Resp. 18–38.

Petitioner calculates the dose that the prior art teaches delivering by inhalation in three separate ways: (1) relying on Voswinckel JESC’s solution concentrations and solution volumes taught by Ex. 1037, (2) relying on Voswinckel JESC’s solution concentrations and solution volumes normally delivered according to the testimony of Petitioner’s declarants, and (3) relying on the ’212 patent’s conversion from an intravascular treprostinil dose to an equivalent inhaled dose. Pet. 22–24, 38–39. According to Petitioner, each of these three calculation methods results in a teaching of a

IPR2021-00406

Patent 10,716,793 B2

therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil. *Id.*

We agree with Patent Owner that Petitioner’s first and third calculation methods do not demonstrate that the prior art taught or suggested a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil, and we do not discuss these calculations any further. The preponderance of the evidence, however, supports Petitioner’s argument that its second calculation demonstrates that the prior art taught or suggested a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil.

Voswinckel JESC teaches that “patients inhaled solvent solution (placebo) (n=8) or treprostinil for 6 min (OptiNeb ultrasound nebulizer, Nebu-tec, Germany) in concentrations of 16, 32, 48, and 64 µg/ml (n=6, 6, 6, and 3 patients).” Ex. 1007, 7. Although this teaching shows administration to patients of inhaled solutions with particular concentrations of treprostinil, it does not disclose the amount of solution administered, which is necessary in order to calculate the amount of treprostinil administered. *Id.* Petitioner directs us to the testimony of its declarants, Dr. Nicholas Hill and Dr. Igor Gonda, to understand how a person of ordinary skill in the art would have interpreted Voswinckel JESC’s disclosure. Pet. 23 (citing Ex. 1002 ¶ 65; Ex. 1004 ¶ 56). Dr. Gonda testifies that “in May 2006 . . . nebulizers conventionally deliver[ed] between 1 and 5 mL” of solution. Ex. 1004 ¶ 56. Relying on Dr. Gonda’s testimony as well as his own experience, Dr. Hill testifies that a person of ordinary skill in the art in 2006 would have understood that “nebulizers . . . nebulize (i.e. aerosolize liquid) at least” 1 mL of solution. Ex. 1002 ¶ 65.



IPR2021-00406  
Patent 10,716,793 B2

Multiplying Voswinckel JESC’s 16, 32, 48, or 64 micrograms of treprostinil per milliliter of solution by the 1 to 5 milliliters of solution in the testimony of Drs. Hill and Gonda, a person of ordinary skill in the art would have interpreted Voswinckel JESC as teaching the delivery of 16–80, 32–160, 48–240, or 64–320 micrograms of treprostinil. Each of those four dose ranges has at least one endpoint that falls within the 15–90 microgram claimed range.

Patent Owner argues that this evidence is insufficient to show that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil. Specifically, Patent Owner argues that the volume of solution that Drs. Hill and Gonda testify was typically used in nebulizers is “the fill volume,” or the amount of solution loaded into a nebulizer to be nebulized, which cannot be used with the concentrations in Voswinckel JESC to arrive at the amount of treprostinil actually delivered to a patient. PO Resp. 30–31. This is because “there is no guarantee that the entire fill volume would be completely nebulized in” the time period over which Voswinckel JESC teaches delivering its dose of treprostinil. *Id.* at 30. In addition, Patent Owner argues that there were other factors that might have caused less than all the solution nebulized by a nebulizer to be actually delivered to the patient, none of which Petitioner accounts for. *Id.* at 31–32.

Petitioner “presented evidence that nebulizers at the time typically involved fill volumes of 1-5mL.” Reply 10–11. To the extent that something less than the entire fill volume was delivered to the patient, either because it was not nebulized or because other factors resulted in the



IPR2021-00406

Patent 10,716,793 B2

nebulized solution not reaching the mouthpiece, the preponderance of the evidence still supports the actual delivered solution volume being at least one milliliter. Dr. Hill testifies that the “at least 1 mL” of solution he discusses is the volume that “nebulizers at the time were known to nebulize,” not the amount of liquid loaded into the nebulizer. Ex. 1002 ¶ 65. Patent Owner’s declarant, Dr. Aaron Waxman, testifies that standard nebulizers had fill volumes of “3 to 5 [milliliters]” and that he had never administered a dose as low as one milliliter to a patient. Ex. 1108, 153:1–22; 156:12–16.

Thus, Voswinckel JESC teaches delivering solution with a treprostinil concentration of 16, 32, 48, or 64 micrograms per milliliter, and the preponderance of the evidence supports a finding that a person of ordinary skill in the art would have understood the volume of solution delivered in Voswinckel JESC to be at least one milliliter. Accordingly, Petitioner has shown by a preponderance of the evidence that Voswinckel JESC teaches or suggests a therapeutically effective single event dose comprising from 15 micrograms to 90 micrograms of treprostinil.

*(4) “Delivered in 1 to 3 breaths”*

Claim 1 recites “delivered in 1 to 3 breaths.” Ex. 1001, 18:31. Petitioner argues that Voswinckel JAHA teaches or suggests this limitation. Pet. 40–41. Patent Owner does not dispute this teaching of Voswinckel JAHA. PO Resp. 10–40.

Voswinckel JAHA teaches delivering to patients “a TRE inhalation by use of the pulsed OptiNeb® ultrasound nebulizer (3 single breaths, TRE solution 600 µg/ml).” Ex. 1008, 3. It also reports that “[t]olerability is excellent even at high drug concentrations and short inhalation times (3

IPR2021-00406

Patent 10,716,793 B2

breaths).” *Id.* Accordingly, Petitioner has shown by a preponderance of the evidence that Voswinckel JAHA teaches or suggests this limitation of claim 1.

b. Reason to Combine with a Reasonable Expectation of Success

As discussed above, Petitioner has shown sufficiently on the present record that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests every limitation of claim 1. This alone is not sufficient to show that the challenged claims would have been obvious; Petitioner also must show that a person of ordinary skill would have had a reason to combine the teachings of the references and would have had a reasonable expectation of success in doing so.

Petitioner argues that a person of ordinary skill in the art would have had a reason to combine the teachings of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–34. Patent Owner argues that a person of ordinary skill in the art would have had “serious concerns about side effects” that would have persuaded them not to combine the teachings of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA. PO Resp. 37–38.

The ’212 patent teaches the use of inhaled treprostinil sodium for the treatment of pulmonary hypertension at doses between 10 and 50 percent of the doses needed for intravascular delivery. Ex. 1006, code (57), 6:1–2, 8:8–12. According to the ’212 patent, the inhaled treprostinil sodium is used in sheep, which are a model for pulmonary hypertension in humans. *Id.* at 9:14–27. Dr. Hill testifies that, based on these teachings, a person of ordinary skill in the art would have looked for further information regarding “experimentation [with] inhaled treprostinil in humans.” Ex. 1002 ¶ 78. On

IPR2021-00406  
Patent 10,716,793 B2

the present record, such information can be found in Voswinckel JESC, which reports on a study in which humans with pulmonary hypertension inhaled treprostinil and experienced “significant long-lasting pulmonary vasodilatation . . . without adverse effects.” Ex. 1007, 7.

Dr. Hill testifies that, based on the teachings of these references a person of ordinary skill would reasonably have expected that treprostinil could safely and effectively treat pulmonary hypertension in humans. Ex. 1002 ¶ 79. Dr. Hill also testifies that a person of ordinary skill in the art “would have been motivated to further decrease the 6 minute administration time in Voswinckel JESC.” Ex. 1002 ¶ 80. Specifically, Dr. Hill testifies that patients often did not adhere to “inhalation therapy for respiratory diseases,” that “[p]oor adherence to medication was known to correlate with worse outcomes,” and that “reducing administration time or the number of breaths required for therapy [was known to] improve adherence rates.” *Id.* (citing Ex. 1002 ¶¶ 36–37; Ex. 1030, 63; Ex. 1032, 179–80; Ex. 1077, 4). Voswinckel JAHA teaches administering treprostinil in three breaths using a high concentration of treprostinil in the aerosolized solution. Ex. 1008, 3. Accordingly, Dr. Hill testifies that a person of ordinary skill in the art would have looked to Voswinckel JAHA to improve patient adherence to the treatment suggested by the combination of the ’212 patent and Voswinckel JESC, providing a reason to combine its teachings with those of the other two references. Ex. 1002 ¶¶ 80–82.

Against this evidence, Patent Owner directs us to the report in Voswinckel JESC that “there were no significant adverse effects” at the lowest treprostinil concentration but that “mild and transient” “[h]e headache, cough or bronchoconstriction were observed” in some patients at higher

IPR2021-00406

Patent 10,716,793 B2

doses, and that one patient at Voswinckel JESC’s highest treprostinil dose “complained of major headache for 1 hour.” Ex. 1007, 7; *see* PO Resp. 37–38. As Patent Owner puts it, “Voswinckel JESC warns in its Conclusion that ‘at a concentration of 16 µg/ml, near maximal pulmonary vasodilation is achieved without adverse effects’ but ‘[a]t higher doses, local and systemic side effects may occur.’” PO Resp. 37–38 (quoting Ex. 1007, 7). Because Petitioner’s proffered reason to combine the teachings of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA requires an increase in treprostinil concentration in order to administer the full dose in three breaths, Patent Owner argues that Voswinckel JESC’s warning about side effects at higher doses would have persuaded a person of ordinary skill in the art not to pursue such a course. *Id.*

The preponderance of the evidence supports Petitioner’s position. Patent Owner is correct that Voswinckel JESC notes that side effects could occur more frequently at higher doses than at lower doses. Ex. 1007, 7. But there is considerable evidence of record that a person of ordinary skill in the art would not have avoided increasing Voswinckel JESC’s dose due to the side effects reported in Voswinckel JESC. First, Dr. Hill testifies that “[p]otential side effects are always weighed against potential clinical benefit, and pulmonary arterial hypertension is a serious, life-threatening disease where physicians and patients are more willing to tolerate side effects . . . to obtain clinical benefit.” Ex. 1106 ¶ 74. Second, Dr. Waxman testifies that “[u]sually the headache goes away” and “there are things that can be done to help ameliorate the cough so in general we are able to get over that issue.” Ex. 1108, 101:19–102:10. Together with Voswinckel JESC’s description of potential side effects as “mild and transient,” this evidence supports a

IPR2021-00406

Patent 10,716,793 B2

finding that a person of ordinary skill in the art would not have been deterred from pursuing the course that is supported by the evidence to which Petitioner directs us.

With respect to reasonable expectation of success, Petitioner argues that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA because Voswinckel JAHA teaches that “[t]olerability is excellent” for its short-duration, high-concentration treprostinil inhalation therapy. Pet. 33 (citing Ex. 1008, 3). Other than the argument discussed above about side effects reported in Voswinckel JESC, Patent Owner does not raise any timely counter to this argument.<sup>8</sup> PO Resp. 10–40. The record supports Petitioner’s argument. Ex. 1008, 3.

Accordingly, Petitioner has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and that they reasonably would have expected to succeed in doing so.

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<sup>8</sup> In the Sur-Reply, Patent Owner raises for the first time three arguments against a reasonable expectation of success. Sur-Reply 21–22 (arguing that a person of ordinary skill in the art would not expect success in delivering Voswinckel JESC’s dose over Voswinckel JAHA’s three breaths because (1) it would require “increas[ing] the number [of] doses per day,” (2) Voswinckel JAHA “lacked any placebo arm,” and (3) Voswinckel JESC and Voswinckel JAHA used patients with differing pulmonary vascular resistances). “A sur-reply may only respond to arguments raised in the corresponding reply.” 37 C.F.R. § 42.23(b). Petitioner’s Reply did not raise any argument regarding a reasonable expectation of success. Reply 1–27. Therefore, we do not consider these newly raised arguments as they exceed the proper scope of the Sur-Reply.

IPR2021-00406

Patent 10,716,793 B2

c. Objective Indicia of Nonobviousness

Patent Owner directs us to evidence of three objective indicia that Patent Owner argues show the nonobviousness of the challenged claims. PO Resp. 55–62. Petitioner argues that the claims would have been obvious despite the evidence to which Patent Owner directs us. Reply 23–27.

*(1) Unexpected Results*

First, Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because they “unexpectedly achieved a therapeutically effective dose that was well tolerated” despite the fact that such “high doses of treprostinil were known in the art to produce dose-limiting side effects.” PO Resp. 55. According to Patent Owner, the challenged claims “produce[d] a new and unexpected result which is different in kind and not merely in degree from the results of the prior art,” which is evidence of those claims’ nonobviousness. *Id.* at 55–57 (quoting *In re Aller*, 220 F.2d 454, 456 (CCPA 1955)). Specifically, Patent Owner argues that the inhaled treprostinil dose recited in the challenged claims represented an increase of “an order of magnitude” over “the maximal tolerated dose” of “intravenous epoprostenol” or “intravenous treprostinil.” *Id.* at 56. Similarly, Patent Owner argues that the challenged claims cover doses of inhaled treprostinil higher than a dose of inhaled iloprost that many patients were unable to tolerate. *Id.* at 56–57.

“[U]nexpected results must establish . . . a difference between the results obtained and those of the closest prior art.” *Bristol-Myers Squibb v. Teva Pharms. USA*, 752 F.3d 967, 977 (Fed. Cir. 2014). Petitioner argues that the prior art over which Patent Owner argues the challenged claims showed unexpected results is not the closest prior art. Reply 24. We agree.

IPR2021-00406

Patent 10,716,793 B2

As noted above, Patent Owner argues that the challenged claims show unexpected results over inhaled iloprost, intravenous epoprostenol, and intravenous treprostinil. PO Resp. 55–57. But the challenged claims recite inhaled treprostinil, and, as discussed above, inhaled treprostinil is taught by each of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.

Ex. 1001, 18:22–44; Ex. 1006, code (57); Ex. 1007, 7; Ex. 1008, 3; Ex. 1035, 582. Patent Owner does not even allege that the results of the challenged claims are unexpected over these references.<sup>9</sup> Accordingly, we find that the evidence of record does not establish that the challenged claims produced a result that was unexpected over the closest prior art.

### *(2) Copying*

Second, Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because Petitioner copied Patent Owner's product, Tyvaso, which is an embodiment of the challenged claims, when Petitioner developed its product, LIQ861. PO Resp. 57–61.

“[F]or objective indicia of nonobviousness to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.” *Lectrosonics, Inc. v. Zaxcom, Inc.*, IPR2018-01129, Paper 33, 32 (PTAB Jan. 24, 2020) (precedential) (citing *ClassCo, Inc. v. Apple, Inc.*, 838 F.3d 1214, 1220 (Fed. Cir. 2016)). A patentee is entitled to a presumption of nexus “when the patentee shows that

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<sup>9</sup> Patent Owner argues that Voswinckel JESC and Voswinckel JAHA are not prior art to the '793 patent. PO Response 44–55; Sur-Reply 2–11, 25. As discussed above, however, Petitioner has shown by a preponderance of the evidence that these references qualify as prior art.



IPR2021-00406  
Patent 10,716,793 B2

the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’” *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (quoting *Polaris Indus., Inc. v. Arctic Cat, Inc.*, 882 F.3d 1056, 1072 (Fed. Cir. 2018) (quoting *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1130 (Fed. Cir. 2000))).

Here, Patent Owner does not allege, let alone “show[]” as required by *Fox Factory*, that Petitioner’s LIQ861 product “is coextensive with” the features claimed in the ’793 patent. 944 F.3d at 1373; *see* PO Resp. 57–61; Sur-Reply 26. Patent Owner does allege that the LIQ861 product embodies the challenged claims, PO Resp. 58–61, and we presume for purposes of our analysis that Patent Owner’s allegation on this issue is correct. But *Fox Factory* requires both a showing that the product in question embodies the claims and a showing that the product in question is coextensive with the claims, and Patent Owner satisfies at most one of those two requirements. Accordingly, we find that a presumption of nexus is inappropriate.

“A finding that a presumption of nexus is inappropriate does not end the inquiry into secondary considerations.” *Fox Factory*, 944 F.3d at 1373. “To the contrary, the patent owner is still afforded an opportunity to prove nexus by showing that the evidence of secondary considerations is the ‘direct result of the unique characteristics of the claimed invention.’” *Id.* at 1373–74 (quoting *In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996)). “Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention,” meaning that “there must be a nexus to



IPR2021-00406  
Patent 10,716,793 B2

some aspect of the claim not already in the prior art.” *In re Kao*, 639 F.3d 1057, 1068–69 (Fed. Cir. 2011) (emphasis in original).

On the other hand, there is no requirement that “objective evidence must be tied exclusively to claim elements that are not disclosed in a particular prior art reference in order for that evidence to carry substantial weight.” *WBIP, LLC v. Kohler Co.*, 829 F.3d 1317, 1331 (Fed. Cir. 2016). A patent owner may show, for example, “that it is the claimed combination as a whole that serves as a nexus for the objective evidence; proof of nexus is not limited to only when objective evidence is tied to the supposedly ‘new’ feature(s).” *Id.* Ultimately, the fact finder must weigh the secondary considerations evidence presented in the context of whether the claimed invention as a whole would have been obvious to a skilled artisan. *Id.* at 1331–32.

Here, Patent Owner directs us to several pieces of evidence that it contends show the LIQ861 product has a nexus to the challenged claims. First, as noted above, Patent Owner argues that LIQ861 embodies those claims. PO Resp. 58–61. Second, Patent Owner notes that “[t]he pharmacokinetics and bioavailability of a 79.5 microgram capsule dose [of LIQ861] was directly compared [by Petitioner] with Patent Owner’s commercial product,” demonstrating that “Petitioner’s commercial product had comparable treprostinil bioavailability with Tyvaso® when delivered in a similar dosage range.” *Id.* at 57–58 (citing Ex. 2085). Third, Patent Owner directs us to the new drug application Petitioner filed with the FDA, “relying in part on FDA’s previous findings of efficacy and safety of Tyvaso® for the treatment of PAH.” *Id.* at 58 (citing Ex. 2089, 3).

IPR2021-00406  
Patent 10,716,793 B2

Taking these pieces of evidence in reverse order, we note first that the new drug application for LIQ861 was filed “under the 505(b)(2) regulatory pathway.” *Id.*; *see also* Reply 25; Ex. 2089, 3. As Petitioner notes, Reply 25, and as Patent Owner does not dispute, Sur-Reply 26, applications for drugs under this pathway do not necessarily copy all aspects of the original drug, but they may rely on the investigations that showed the safety and efficacy of the original drug that uses the same active ingredient. 21 U.S.C. § 355(b)(2). In this respect, they differ from applications under the § 505(j) regulatory pathway, under which the new drug must generally have the same “active ingredient,” “route of administration,” “dosage form,” “strength,” and “labeling” as the original drug. 21 U.S.C. § 355(j)(2). Because the challenged claims here recite limitations requiring administration by inhalation of a particular amount of treprostinil in a particular number of breaths (and in some cases using a particular type of device and with the drug in a particular form), evidence that Petitioner merely relied on previous studies of the safety and efficacy of the recited active ingredient is not particularly strong evidence of copying.

Next, we consider the evidence that Petitioner compared the pharmacokinetics and bioavailability of its LIQ861 product with those of Patent Owner’s Tyvaso product. Ex. 2085. Patent Owner argues that this evidence shows that “Petitioner’s commercial product had comparable treprostinil bioavailability with Tyvaso® when delivered in a similar dosage range.” PO Resp. 57–58. Regardless of whether an objective indicium of nonobviousness has its nexus to a single “aspect of the claim not already in the prior art,” *Kao*, 639 F.3d at 1068–69, or to “the claimed combination as a whole,” *WBIP*, 829 F.3d at 1331, it still must have some nexus to the claim

IPR2021-00406  
Patent 10,716,793 B2

in question. The challenged claims, however, do not recite any limitations for treprostinil bioavailability or pharmacokinetics. Ex. 1001, 18:22–44. Accordingly, evidence that Petitioner formulated its product to have similar bioavailability and pharmacokinetics to Patent Owner’s product is, at most, very weak evidence of copying as to the claims at issue here.

Finally, we consider the evidence that LIQ861 embodies the challenged claims. PO Resp. 58–61. “Not every competing product that arguably falls within the scope of a patent is evidence of copying; otherwise, ‘every infringement suit would automatically confirm the nonobviousness of the patent.’” *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (quoting *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1325 (Fed. Cir. 2004)). Proof of copying requires “actual evidence of copying efforts as opposed to mere allegations regarding similarities between the accused product and a patent.” *Liqwd, Inc. v. L’Oreal USA, Inc.*, 941 F.3d 1133, 1137–38 (Fed. Cir. 2019). Thus, evidence that LIQ861 embodies the challenged claims is not evidence that could, without more, support a finding that Petitioner copied Patent Owner’s patented method. As discussed above, to the extent there is any evidence of what *Liqwd* refers to as “copying efforts” beyond mere similarity between LIQ861 and the challenged claims, that evidence shows that Petitioner copied only features that appear in the prior art, are not recited in the challenged claims, or both. Accordingly, we do not find that Patent Owner has shown that Petitioner copied the method of the challenged claims.

### *(3) Long-Felt and Unmet Need*

Patent Owner directs us to evidence that allegedly demonstrates that the challenged claims would have been nonobvious because “[t]he claimed

IPR2021-00406  
Patent 10,716,793 B2

invention of the '793 patent satisfies a long-felt unmet need in the treatment of pulmonary hypertension.” PO Resp. 61–62; *see* Sur-Reply 26. Patent Owner relies on three separate theories to demonstrate this long-felt need. First, in the Response, Patent Owner argues that the approval of inhaled treprostinil as the first treatment for “pulmonary hypertension associated with interstitial lung disease” satisfied “a completely unmet medical need.” PO Resp. 61–62 (quoting Ex. 2056, 105:6–8). Second, also in the Response, Patent Owner argues that Petitioner admitted that its LIQ861 product “fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler.” *Id.* at 62 (quoting Ex. 2085). Third, in the Sur-Reply, Patent Owner argues that its Tyvaso product satisfied a need for an “inhaled treatment for pulmonary hypertension” that avoided the “inconvenient dosing and side effects of Ventavis,” the only previously approved treatment. Sur-Reply 26 (citing Ex. 1002 ¶ 42; Ex. 1108, 44:19–21, 49:17–50:10; Ex. 2055, 28:22–29:20). Each of these arguments fails for a different reason.

We begin with Patent Owner’s third argument, that Tyvaso satisfied a need for an inhaled treatment that avoided the dosing problems and side effects of Ventavis. Patent Owner offers this argument for the first time in the Sur-Reply. *Id.* “A sur-reply may only respond to arguments raised in the corresponding reply.” 37 C.F.R. § 42.23(b). “‘Respond,’ in the context of 37 C.F.R. § 42.23(b), does not mean proceed in a new direction with a new approach as compared to the positions taken in a prior filing.” Patent Trial and Appeal Board Consolidated Trial Practice Guide 74 (Nov. 2019), available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>.

IPR2021-00406  
Patent 10,716,793 B2

As discussed in more detail below, in its prior filings, Patent Owner’s only positions with respect to long-felt need were (1) that the patented method satisfied a need for a treatment for pulmonary hypertension associated with interstitial lung disease and (2) that Petitioner admitted that its product satisfied a need. PO Resp. 61–62. Neither of those positions related to a need for a treatment that avoided the problems associated with Ventavis. *Id.* Accordingly, Patent Owner’s argument in the Sur-Reply is a new argument that we do not consider further.

Next, we consider Patent Owner’s argument that the method of the ’793 patent provided the first treatment for pulmonary hypertension associated with interstitial lung disease. *Id.* Even if this is true, it is extremely weak evidence of the nonobviousness of the claims at issue because those claims do not cover treatment of pulmonary hypertension associated with interstitial lung disease. There are multiple groups of pulmonary hypertension conditions. Ex. 1088, 1. In addition to other groups not relevant here, these groups include “WHO Group 1,” or “[p]ulmonary arterial hypertension,” and “WHO Group 3,” or “[p]ulmonary hypertension associated with interstitial lung disease.” *Id.* Patent Owner’s declarant, Dr. Waxman, testifies that all pulmonary hypertension groups other than Group 1 fall outside the scope of the claims of the ’793 patent. Ex. 1132, 116:9–119:12. Dr. Hill agrees. Ex. 1106 ¶ 100. Thus, to the extent the challenged claims satisfied a long-felt and unmet need for a treatment for pulmonary hypertension associated with interstitial lung disease, Patent Owner has not shown that that need is tied to any limitation of the challenged claims or to any challenged claim as a whole.

IPR2021-00406

Patent 10,716,793 B2

Finally, we consider Patent Owner’s argument that Petitioner admitted that its LIQ861 product “fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler.” PO Resp. 62 (quoting Ex. 2085). “Evidence of a long-felt but unresolved need can weigh in favor of the non-obviousness of an invention because it is reasonable to infer that the need would not have persisted had the solution been obvious.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1056 (Fed. Cir. 2016). Patent Owner directs us to two pieces of evidence. First, Patent Owner directs us to Exhibit 2085, which states that LIQ861 “fulfill[ed] a significant unmet need for PAH patients by maximizing the therapeutic benefits of treprostinil by safely delivering doses to the lungs in 1 to 2 breaths using a discreet, convenient, easy-to-use inhaler.” Ex. 2085, 1. This demonstrates that Petitioner believed its product satisfied a particular “significant unmet need,” but it does not demonstrate how long that need persisted. *Id.* Second, Patent Owner directs us to page F-7 of Exhibit 2089, but this page does not address the filling of any need by LIQ861. Ex. 2089, F-7. Thus, Patent Owner does not show that any previously unmet need satisfied by LIQ861 was a need that had persisted, as required by *Apple v. Samsung*. Accordingly, we do not find that Patent Owner has shown that the patented method satisfied any previously unmet and long-felt need.

#### d. Dependent Claims

Claims 2–8 of the ’793 patent depend directly or indirectly from claim 1. Ex. 1001, 18:32–45. Petitioner argues that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests

IPR2021-00406  
Patent 10,716,793 B2

the additional limitations of these claims. Pet. 41–46. Patent Owner does not dispute these arguments, except with respect to claims 4, 6, and 7. PO Resp. 38–40.

We have reviewed the evidence cited by Petitioner with respect to dependent claims 2, 3, 5, and 8, and we are persuaded that Petitioner has shown by a preponderance of the evidence that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of these claims. For example, claim 2 depends from claim 1 and recites a further limitation that requires that “the inhalation device [be] a soft mist inhaler,” and Petitioner directs us to evidence that soft mist inhalers were known in the prior art, as well as evidence that soft mist inhalers were known to be suitable for inhaled delivery of drugs in a small number of breaths. Ex. 1001, 7:33–39, 18:32–33; Ex. 1002 ¶¶ 106–110; Ex. 1004 ¶¶ 66–71; Ex. 1006, 5:30–32; Ex. 1034, 175.

The parties dispute the obviousness of claims 4, 6, and 7. Claim 4 depends from claim 1 and recites a limitation requiring that “the inhalation device [be] a dry powder inhaler.” Ex. 1001, 18:36–37. Claim 6 depends from claim 4 and adds a limitation requiring that “the formulation [be] a powder.” *Id.* at 18:40–41. Claim 7 depends from claim 6 and adds a limitation requiring that “the powder comprise[] particles less than 5 micrometers in diameter.” *Id.* at 18:42–43. Petitioner argues that each of these limitations is taught or suggested by the ’212 patent. Pet. 43–45 (citing Ex. 1006, 5:30–32, 5:37–41, 14:19–21; Ex. 1002 ¶¶ 116–117; Ex. 1004 ¶¶ 77–80; Ex. 1038, 311). Patent Owner argues that Petitioner’s obviousness argument with respect to these claims is inconsistent with Petitioner’s argument in the parallel District Court proceeding that these



IPR2021-00406

Patent 10,716,793 B2

claims are not enabled. PO Resp. 38–40. Specifically, Patent Owner argues that Dr. Gonda’s testimony here that a person of ordinary skill in the art “would have had a reasonable expectation of success that the ‘powder’ disclosed and claimed in the ’212 Patent could be ‘inhaled’ by a patient using a dry powder inhaler” contradicts Dr. Gonda’s testimony in District Court that a person of ordinary skill in the art “would be unable to formulate a treprostinil powder suitable for administration via a dry powder inhaler for [pulmonary hypertension] patients without excessive experimentation.” PO Resp. 38–39 (quoting Ex. 1004 ¶ 80; Ex. 2091, 40–61). Because Dr. Gonda’s District Court testimony is more “lengthy” than his testimony here, Patent Owner argues that the District Court testimony is more reliable and that, accordingly, we should not rely on Dr. Gonda’s testimony here. *Id.* at 40.

Dr. Gonda’s testimony here provides support for Petitioner’s argument that a person of ordinary skill in the art would have had a reasonable expectation of success in combining the teachings of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA in order to arrive at the invention of claims 4, 6, and 7. Ex. 1004 ¶ 80. Reasonable expectation of success is a separate inquiry from enablement. *UCB, Inc. v. Accord Healthcare, Inc.*, 890 F.3d 1313, 1327 (Fed. Cir. 2018) (finding no “authority for the proposition that the presumption of” enablement of prior art “precludes . . . finding that there was no reasonable expectation of success”). Accordingly, the mere fact that Dr. Gonda testifies to a lack of enablement in one forum and to the presence of a reasonable expectation of success in a second forum does not render unreliable the testimony in either forum. Therefore, we credit the unrebutted testimony of Dr. Gonda that a



IPR2021-00406  
Patent 10,716,793 B2

person of ordinary skill in the art “would have had a reasonable expectation of success that the ‘powder’ disclosed and claimed in the ’212 Patent could be ‘inhaled’ by a patient using a dry powder inhaler.” Ex. 1004 ¶ 80. In addition, Dr. Gonda’s testimony in this proceeding is supported by a citation to Ex. 1038, an October 2005 article that states that dry powder inhalers “are a widely accepted inhaled delivery dosage form,” as well as to Ex. 1019, an article stating that 14 separate dry powder inhalers were approved in the United States by 2006. Ex. 1019, 33; Ex. 1038, 1311. This evidence provides us with an additional reason to credit Dr. Gonda’s testimony as to reasonable expectation of success.

Moreover, even if there were some connection between enablement and reasonable expectation of success, Patent Owner concedes that the ’212 patent enables its own claims. Tr. 43:6–50:9. In other words, the ’212 patent provides enough information for a person of ordinary skill in the art to have made and used the invention defined by the claims of the ’212 patent. *See* 35 U.S.C. § 112. That invention includes “[a] method for treating pulmonary hypertension in a mammal comprising delivering to said mammal an effective amount of [treprostinil] or its pharmaceutically acceptable salt or ester by inhalation,” wherein the treprostinil “is inhaled in powder form comprising particles less than 10 micrometers in diameter.” Ex. 1006, 14:9–12, 14:19–21. To the extent that, despite *UCB*, 890 F.3d at 1327, there remains any connection at all between a reasonable expectation of success and enablement, the fact that a person of ordinary skill in the art was enabled to make and use this invention presumably would have rendered that person more likely to expect success in achieving the similar invention of claims 4, 6, and 7 of the ’793 patent.

IPR2021-00406  
Patent 10,716,793 B2

Further, as discussed above with respect to the reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA, Petitioner directs us to other evidence that a person of ordinary skill in the art would have had a reasonable expectation of success.

For all these reasons, we determine that Petitioner has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the '212 patent, Voswinckel JESC, and Voswinckel JAHA and would have had a reasonable expectation of success in doing so in order to arrive at the invention of the challenged claims, including claims 4, 6, and 7.

Thus, we move on to whether the prior art teaches or suggests the additional limitations of claims 4, 6, and 7. Petitioner argues that the '212 patent teaches or suggests each of these limitations, and Patent Owner does not dispute that argument. Pet. 43–45; PO Resp. 38–40. Claim 4 recites a limitation requiring that “the inhalation device [be] a dry powder inhaler.” Ex. 1001, 18:36–37. The '212 patent teaches using an “inhaler” to deliver treprostinil, that “solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention,” and that treprostinil “is inhaled in powder form.” Ex. 1006, 5:30–32, 5:37–39, 14:19–21. Dr. Hill testifies that a person of ordinary skill in the art would have known that the “inhaler” used to deliver the “powder” of the '212 patent was a dry powder inhaler. Ex. 1002 ¶ 116. Claim 6 depends from claim 4 and adds a limitation requiring that “the formulation [be] a powder.” Ex. 1001, 18:40–41. The '212 patent teaches that “solid formulations, usually in the form of a powder, may be inhaled in accordance with the present invention,” as well as that treprostinil “is inhaled in powder form.” Ex. 1006, 5:37–39, 14:19–

IPR2021-00406

Patent 10,716,793 B2

21. Claim 7 depends from claim 6 and adds a limitation requiring that “the powder comprise[] particles less than 5 micrometers in diameter.” Ex. 1001, 18:42–43. The ’212 patent teaches that “the particles are preferably less than 10 micrometers in diameter, and more preferably, less than 5 micrometers in diameter.” Ex. 1006, 5:39–41. Accordingly, Petitioner has shown by a preponderance of the evidence that the ’212 patent teaches or suggests the additional limitations of claims 4, 6, and 7 of the ’793 patent.

e. Conclusion

As discussed above, Petitioner has shown by a preponderance of the evidence that the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA teaches or suggests the subject matter of claims 1–8. Petitioner also has shown by a preponderance of the evidence that a person of ordinary skill in the art would have had a reason to combine the teachings of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA and would have had a reasonable expectation of success in doing so to arrive at the invention of the challenged claims. In addition, the preponderance of the evidence shows that there is at most very weak evidence of objective indicia of nonobviousness, including unexpected results, copying, and long-felt but unmet need. Weighing together the evidence of the prior art teaching or suggesting the subject matter of the claims, of a reason to combine the teachings of the prior art with a reasonable expectation of success, and of objective indicia of nonobviousness, we conclude that Petitioner has demonstrated that claims 1–8 of the ’793 patent would have been obvious over the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA and, accordingly, that those claims are unpatentable.

IPR2021-00406

Patent 10,716,793 B2

*C. Asserted Obviousness over '212 Patent and Voswinckel JESC*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent and Voswinckel JESC. Pet. 46–50. Because Petitioner has shown by a preponderance of the evidence that all of the challenged claims would have been obvious over the similar combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA, we need not reach this asserted ground.

*D. Grounds Relying on Ghofrani or Voswinckel 2006*

Petitioner argues that claim 1 was anticipated by Ghofrani; that claims 1, 3, and 8 would have been obvious over the combination of Voswinckel JAHA and Ghofrani; that claims 1 and 3 were anticipated by Voswinckel 2006; and that claims 2 and 4–8 would have been obvious over the combination of Voswinckel 2006 and the '212 patent. Pet. 50–64. Patent Owner argues that each of these grounds fails because Petitioner fails to show sufficiently that Ghofrani and Voswinckel 2006 qualify as prior art. PO Resp. 44–54. Petitioner disagrees, arguing that these references qualify as prior art under 35 U.S.C. § 102(a). Pet. 25–30.

In the institution decision, we determined that, on the preliminary record available at the time, Petitioner had not shown that either Ghofrani or Voswinckel 2006 qualified as prior art. Inst. Dec. 37–43. Since that decision, Petitioner has neither supplemented the record nor made any additional arguments on this issue. Reply 1–27. During the hearing, Petitioner did not agree that it had abandoned its argument on the grounds asserting Ghofrani or Voswinckel 2006. Tr. 35:13–36:10. Nevertheless, in the absence of any new evidence or argument, we have been directed to nothing that persuades us to reach any decision other than we reached

IPR2021-00406  
Patent 10,716,793 B2

initially. Accordingly, our analysis below mirrors the analysis we conducted in the institution decision.

*1. Prior-Art Status of Ghofrani*

Ghofrani is an article published in the German journal Herz in June 2005, less than one year before the priority date of the '793 patent. Pet. 25; Ex. 1010, 9; Ex. 1036 ¶¶ 47–55. Petitioner argues that Ghofrani is prior art to the '793 patent under 35 U.S.C. § 102(a). Pet. 25–27. Patent Owner disagrees, arguing that Petitioner has not shown sufficiently that Ghofrani is “by others” under § 102(a). PO Resp. 44–51.

As both parties acknowledge, establishing prior-art status under § 102(a) requires showing that the reference is “by others,” meaning that it was authored by an entity different from the entity that invented the challenged patent. Pet. 26–27; PO Resp. 44–46; *see Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*, 322 F.3d 1335, 1346 (Fed. Cir. 2003) (“it is well-settled law that an inventor’s own disclosure will not anticipate his later invention” unless published more than one year prior to the priority date (internal quotation marks omitted)).

The authors of Ghofrani are “Hossein Ardeschir Ghofrani, Robert Voswinckel, Frank Reichenberger, Friedrich Grimminger, [and] Werner Seeger.” Ex. 1010, 9. The inventors of the '793 patent are Horst Olschewski, Robert Roscigno, Lewis J. Rubin, Thomas Schmehl, Werner Seeger, Carl Sterritt, and Robert Voswinckel. Ex. 1001, code (72). Thus, there are, as Petitioner argues, “inventors listed on the '793 Patent that are not listed as authors on Ghofrani, and vice versa.” Pet. 26. Specifically, Ghofrani, Reichenberger, and Grimminger authored the Ghofrani reference but were not inventors of the '793 patent; and Olschewski, Roscigno, Rubin,

IPR2021-00406  
Patent 10,716,793 B2

Schmehl, and Sterritt were inventors of the '793 patent but not authors of the Ghofrani reference.

Petitioner argues that these differences alone are sufficient to show that Ghofrani is “by others.” *Id.* at 26–27. We agree that it is possible, depending on the state of the rest of the evidence of record, for any difference between the authors of an alleged prior-art reference and the inventors of a challenged patent to render the reference “by others” for purposes of § 102(a). *See, e.g., In re Katz*, 687 F.2d 450, 455 (CCPA 1982) (“ambiguity [was] created by the printed publication” where authors included people not named as inventors); *cf. In re Land*, 368 F.2d 866, 877 (CCPA 1966) (for purposes of § 102(e), reference authored by one co-inventor was “by another”).

That said, it is not always sufficient for Petitioner merely to show a difference between a list of authors and a list of inventors. Where the record contains evidence that the reference was derived entirely from the work of the inventors or at least one joint inventor, this evidence may be sufficient to show that the reference is not “by others” for purposes of § 102(a). *Katz*, 687 F.2d at 455–56 (finding inventor’s declaration of sole inventorship sufficient to render reference authored by inventor and others not “by others”). Although the testimony of an inventor that the reference in question was derived from the inventors’ work may be sufficient on its own, at least where it is not “a mere pro forma restatement of the oath in [the inventor’s] application,” affidavits from the other authors disclaiming the invention are particularly strong evidence that the reference is not “by others.” *Id.* (“Submission of such affidavits or declarations would have ended the inquiry . . .”). Here, for the reasons discussed below, the

IPR2021-00406  
Patent 10,716,793 B2

preponderance of the evidence persuades us that, despite the differences between its list of authors and the list of the inventors of the '793 patent, Ghofrani is not “by others” for purposes of § 102(a).

Petitioner’s first argument that Ghofrani is “by others” is that there are people who are authors of Ghofrani who are not inventors of the '793 patent. Pet. 26. But Dr. Seeger, one of the inventors of the '793 patent, as well as an author of Ghofrani, describes the roles of the other authors of Ghofrani, explaining that Dr. Ghofrani drafted the portion of the article “relating to phosphodiesterase inhibitors,” that Drs. Reichenberger and Grimminger drafted the portion of the article relating to “the use of selective endothelin A receptor agonists for treating pulmonary hypertension,” and that he and Dr. Voswinckel—another co-inventor—drafted the portion of the article relating to “the use of inhaled iloprost and inhaled treprostinil for treatment of pulmonary hypertension,” the only portion on which Petitioner’s unpatentability case rests. Ex. 2003 ¶¶ 4–8. Dr. Seeger’s testimony is corroborated by the testimony of Drs. Ghofrani, Reichenberger, and Grimminger, each of whom testifies that they “did not make material contributions to” the portion of the Ghofrani reference relating to inhaled treprostinil. Ex. 2004 ¶¶ 4–5; Ex. 2005 ¶¶ 4–5; Ex. 2006 ¶¶ 4–5. This is precisely the type of testimony that the *Katz* court held should “end[] the inquiry” into whether Ghofrani was “by others.” 687 F.2d at 455–56. Accordingly, this evidence overcomes Petitioner’s argument that the difference between the Ghofrani authors and the inventors of the '793 patent is sufficient to show that Ghofrani is “by others.”

Petitioner also argues that the failure to include some of the inventors of the '793 patent—Olschewski, Roscigno, Rubin, Schmehl, and Sterritt—as



IPR2021-00406

Patent 10,716,793 B2

authors of Ghofrani renders Ghofrani “by others.” Pet. 26–27. But “the fact that a reference does not list any co-inventors as authors . . . is certainly not dispositive in itself.” *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 969 (Fed. Cir. 2014); see MPEP § 2132.01(I) (“An inventor’s or at least one joint inventor’s disclosure of his or her own work within the year before the application filing date cannot be used against the application as prior art under pre-AIA 35 U.S.C. 102(a).”). Moreover, Dr. Seeger explains the roles of the other named inventors in designing trials and clinical studies leading to the patent application. Ex. 2003 ¶¶ 22–27. In particular, Dr. Seeger testifies that the Ghofrani reference did not report on the details of the studies and trials that were in part designed by these other authors, explaining why they did not contribute to writing Ghofrani, even though they were involved in the related work that gave rise to the ’793 patent. *Id.* ¶¶ 11–12. Dr. Seegar further explains that, “any study that formed the basis of our discussion of inhaled trepostinil in [Ghofrani and two other references] was performed by me in conjunction with my ongoing collaboration with Drs. Voswinckel, Olschewski, Rubin, Schmehl, Sterrit, and Roscigno.” *Id.* ¶ 12. Again, then, the preponderance of the evidence supports a determination that Ghofrani is not “by others” for purposes of § 102(a).

## 2. *Prior-Art Status of Voswinckel 2006*

The issues and arguments regarding Voswinckel 2006 are quite similar to those discussed above regarding Ghofrani. Petitioner argues that Voswinckel 2006 qualifies as prior art under § 102(a) and that it is “by others” both because some of its authors—specifically, Ghofrani and Grimminger—are not inventors of the ’793 patent and because some



IPR2021-00406  
Patent 10,716,793 B2

inventors of the '793 patent—specifically, Olschewski, Roscigno, Rubin, Schmehl, and Sterritt—are not authors of Voswinckel 2006. Pet. 27–30. Patent Owner disagrees, pointing to the testimony of Drs. Seeger, Ghofrani, and Grimminger explaining the role that the other inventors of the '793 patent played, as well as making clear that neither Ghofrani nor Grimminger authored the portion of Voswinckel 2006 that is relevant as prior art. PO Resp. 44–46, 51–54; Ex. 2003 ¶¶ 20–21 (describing the roles of Drs. Ghofrani and Grimminger, explaining that they “did not participate in the design of any of the studies, did not select the dosing regimen, and did not conduct analysis of patient results discussed in . . . Voswinckel 2006”); 19 (“any study that formed the basis of our discussion of inhaled treprostinil in this reference was performed by me in connection with my ongoing collaboration with [the other inventors]”).

For the same reasons discussed above with respect to Ghofrani, we determine that the preponderance of the evidence shows that Petitioner has not shown sufficiently that Voswinckel 2006 is “by others.”

### 3. *Conclusion*

For the reasons discussed above, Petitioner has not shown that either Ghofrani or Voswinckel 2006 qualifies as prior art. Accordingly, Petitioner has not shown the unpatentability of any challenged claim on any ground that relies on either Ghofrani or Voswinckel 2006.

#### *E. Motions to Exclude Evidence*

Each party filed a motion to exclude evidence. Paper 65; Paper 66. We consider each motion separately below.

IPR2021-00406  
Patent 10,716,793 B2

1. *Petitioner's Motion to Exclude*

Petitioner moves to exclude Exhibits 2092, 2100, 2101, 2102, and 2103 as not authenticated and, for Ex. 2092, as incomplete. Paper 65, 1. Petitioner also moves to exclude the portions of Patent Owner's Sur-Reply that rely on these exhibits. *Id.*

We do not rely on any of the exhibits Petitioner challenges in reaching our decision in this case. Accordingly, we dismiss Petitioner's motion to exclude as moot.

2. *Patent Owner's Motion to Exclude*

Patent Owner moves to exclude Exhibits 1037, 1114, 1117, and 1120 as hearsay and, for Ex. 1037, as not authenticated, irrelevant, and lacking the original writing. Paper 66, 2. Patent Owner also moves to exclude Exhibits 1029, 1050, 1066, 1074, and 1078 as not authenticated. *Id.* Patent Owner moves to exclude Exhibit 1087 as lacking personal knowledge and as irrelevant. *Id.* Patent Owner also moves to exclude portions of Exhibit 1112 as not based on sufficient facts and analysis. *Id.* Further, Patent Owner moves to exclude the portions of Petitioner's Petition and Reply, as well as the portions of Exhibits 1002 and 1004, that cite these exhibits. *Id.* at 2–3.

We do not rely on any of the exhibits or portions of exhibits Patent Owner moves to exclude in reaching our decision in this case, with two exceptions: paragraphs 36 and 42 of Ex. 1002, which cite Ex. 1029, and paragraph 56 of Ex. 1004, which Patent Owner argues cites Ex. 1029, Ex. 1050, and Ex. 1066. We dismiss as moot Patent Owner's motion to exclude, except as to these paragraphs of Exhibits 1002 and 1004. We discuss the remaining portions of Patent Owner's motion to exclude below.

IPR2021-00406  
Patent 10,716,793 B2

a. Paragraphs 36 and 42 of Exhibit 1002

Patent Owner moves to exclude paragraphs 36 and 42 of Exhibit 1002 because they rely on Exhibit 1029, which Patent Owner argues lacks authentication. Paper 66, 2–3.

Certain items are self-authenticating under Federal Rule of Evidence (“FRE”) 902, and, for items that are not self-authenticating, FRE 901 provides that “the proponent [of the evidence in question] must produce evidence sufficient to support a finding that the item is what the proponent claims it is.” Fed. R. Evid. 901(a). The evidence showing “that the items is what the proponent claims it is” may include “[t]estimony that an item is what it is claimed to be,” or “[t]he appearance, contents, substance, internal patterns, or other distinctive characteristics of the item, taken together with all the circumstances,” among other things. Fed. R. Evid. 901(b).

Here, Dr. Hill, Petitioner’s declarant, testifies three times that Exhibit 1029 is the “Ventavis Label 2004.” Ex. 1002 ¶¶ 36, 41, 42. Dr. Gonda, another declarant for Petitioner, testifies that Exhibit 1029 is the “Ventavis (iloprost) Label.” Ex. 1004 ¶ 56 n.4. Dr. Waxman, Patent Owner’s declarant, cites to Exhibit 1029 twice as support for the approved dose for, and side effects experienced by, patients taking Ventavis. Ex. 2052 ¶ 100. The “appearance, contents, substance, internal patterns, [and] other distinctive characteristics,” Fed. R. Evid. 901(b), of Ex. 1029 confirm the testimony of Drs. Hill, Gonda, and Waxman. The document contains sections titled “description,” “clinical pharmacology,” “indications and usage,” “contraindications,” “warnings,” “precautions,” “adverse reactions,” “overdosage,” “dosage and administration,” “how supplied,” “storage,” and “patient information,” with each section providing information related to

IPR2021-00406  
Patent 10,716,793 B2

“Ventavis.” Ex. 1029, 1–17. This information is consistent with a drug label for Ventavis, which is what Dr. Hill and Dr. Gonda testify, what Dr. Waxman assumes, and what Petitioner argues, Ex. 1029 is. Accordingly, we find that Petitioner has “produce[d] evidence sufficient to support a finding that [Ex. 1029] is what [Ppetitioner] claims it is.” Fed. R. Evid. 901(a). Because Ex. 1029 does not lack authentication, we deny Patent Owner’s motion to exclude paragraphs 36 and 42 of Ex. 1002, which cite to Ex. 1029.

b. Paragraph 56 of Exhibit 1004

Patent Owner moves to exclude paragraph 56 of Exhibit 1004 because it relies on Exhibits 1029, 1050, and 1066, all of which Patent Owner argues lack authentication. Paper 66, 2–3. We discuss Exhibit 1029 above, finding that it is sufficiently authenticated. The situation with respect to Exhibits 1050 and 1066 is similar. Dr. Gonda testifies that Ex. 1050 is the “Pulmozyme® Label” and that Ex. 1066 is the “AccuNeb® Label.” Ex. 1004 ¶ 56 n.4. Moreover, Dr. Gonda’s testimony about what Exhibits 1050 and 1066 are is confirmed by the contents of those exhibits. Exhibit 1050 contains sections titled “description,” “clinical pharmacology,” “indications and usage,” “contraindications,” “warnings,” “precautions,” “adverse reactions,” “overdosage,” “dosage and administration,” and “how supplied,” with each section providing information related to “Pulmozyme.” Ex. 1050, 1–2. Exhibit 1066 contains sections titled “description,” “clinical pharmacology,” “indications and usage,” “contraindications,” “warnings,” “precautions,” “adverse reactions,” “overdosage,” “dosage and administration,” “how supplied,” “storage,” and “patient’s instructions for use,” with each section providing information related to “AccuNeb.”

IPR2021-00406

Patent 10,716,793 B2

Ex. 1066, 1–2. This information is consistent with drug labels for Pulmozyme and AccuNeb, which is what Dr. Gonda testifies, and what Petitioner argues, Exhibits 1050 and 1066 are. Accordingly, we find that Petitioner has “produce[d] evidence sufficient to support a finding that [Ex. 1050 and Ex. 1066 are] what [Petitioner] claims [they are].” Fed. R. Evid. 901(a). Because Exhibits 1050 and 1066 do not lack authentication, we deny Patent Owner’s motion to exclude paragraph 56 of Ex. 1004, which cites to those exhibits.

IPR2021-00406  
Patent 10,716,793 B2

## CONCLUSION<sup>10</sup>

For the reasons discussed above, Petitioner has shown by a preponderance of the evidence that claims 1–8 of the ’793 patent are unpatentable.

Claims	35 U.S.C. §	Reference(s)/Basis	Claims Shown Unpatentable	Claims Not Shown Unpatentable
1–8	103(a)	’212 patent, Voswinckel JESC, Voswinckel JAHA	1–8	
1–8	103(a)	’212 patent, Voswinckel JESC <sup>11</sup>		
1	102(a)	Ghofrani		1
1, 3, 8	103(a)	Voswinckel JAHA, Ghofrani		1, 3, 8
1, 3	102(a)	Voswinckel 2006		1, 3
2, 4–8	103(a)	Voswinckel 2006, ’212 patent		2, 4–8
<b>Overall Outcome</b>			1–8	

<sup>10</sup> Should Patent Owner wish to pursue amendment of the challenged claims in a reissue or reexamination proceeding subsequent to the issuance of this Decision, we draw Patent Owner’s attention to the April 2019 Notice Regarding Options for Amendments by Patent Owner Through Reissue or Reexamination During a Pending AIA Trial Proceeding. *See* 84 Fed. Reg. 16,654 (Apr. 22, 2019). If Patent Owner chooses to file a reissue application or a request for reexamination of the challenged patent, we remind Patent Owner of its continuing obligation to notify the Board of any such related matters in updated mandatory notices. *See* 37 C.F.R. §§ 42.8(a)(3), (b)(2).

<sup>11</sup> This Final Written Decision does not reach these grounds because Petitioner has proven all challenged claims are unpatentable based on obviousness over the combination of the ’212 patent, Voswinckel JESC, and Voswinckel JAHA.

IPR2021-00406  
Patent 10,716,793 B2

## ORDER

It is hereby

ORDERED that, based on the preponderance of the evidence, claims 1–8 of the '793 patent have been shown to be unpatentable;

FURTHER ORDERED that Petitioner's Motion to Exclude is dismissed as moot;

FURTHER ORDERED that Patent Owner's Motion to Exclude is denied as to paragraphs 36 and 42 of Exhibit 1002 and as to paragraph 56 of Exhibit 1004;

FURTHER ORDERED that Patent Owner's Motion to Exclude is dismissed as moot in all other respects; and

FURTHER ORDERED that, because this is a Final Written Decision, parties to this proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

IPR2021-00406  
Patent 10,716,793 B2

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IPR2021-00406  
Patent 10,716,793 B2

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# EXHIBIT 3

[Trials@uspto.gov](mailto:Trials@uspto.gov)  
571-272-7822

Paper 81  
Date October 26, 2022

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,  
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,  
Patent Owner.

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IPR2021-00406  
Patent 10,716,793 B2

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Before KATHERINE K. VIDAL, *Under Secretary of Commerce for  
Intellectual Property and Director of the United States Patent and  
Trademark Office*, SCOTT R. BOALICK, *Chief Administrative Patent  
Judge*, and JACQUELINE WRIGHT BONILLA, *Deputy Chief  
Administrative Patent Judge*.

PER CURIAM.

ORDER

IPR2021-00406

Patent 10,716,793 B2

The Office received a request for Precedential Opinion Panel (POP) review of issues raised in the Board’s Final Written Decision. Ex. 3003; *see* Paper 78. In the request, Patent Owner argues that the Board improperly determined that the Voswinckel JESC (Ex. 1007) and Voswinckel JAHA (Ex. 1008) references were publicly accessible and therefore qualify as prior art under pre-AIA 35 U.S.C. § 102(b) because a person of ordinary skill in the art would have been able to find them with the benefit of certain research aids. Paper 79, 1–3; *see* Paper 78, 8–12. The request was referred to the POP panel referenced above.

We have reviewed the request, the Board’s Final Written Decision, the Papers, and the Exhibits in the above-listed proceeding. We determine that the Board’s Final Written Decision did not address adequately whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art. *See* Paper 78, 8–12. Specifically, the Board’s analysis did not consider whether the research aids themselves were available prior to the critical date, such that a person of ordinary skill in the art would have used them to find Voswinckel JESC and Voswinckel JAHA. *Id.* at 12. Further, the Board’s analysis did not address whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library. Paper 78, 8–12; *see In re Klopfenstein*, 380 F.3d 1345, 1350–52 (Fed. Cir. 2004) (“The determination of whether a reference is a ‘printed publication’ under 35 U.S.C. § 102(b) involves a case-by-case inquiry into the facts and circumstances surrounding the reference’s disclosure to members of the public.”).

IPR2021-00406

Patent 10,716,793 B2

However, because the record has been fully developed on these issues, the Board panel is best suited to make the appropriate factual findings for this analysis in its decision on rehearing. Accordingly, we deny Patent Owner's request for POP review of the Final Written Decision. With this denial of POP review, authority over all issues in this case — including consideration of Patent Owner's pending rehearing request — is returned to the original panel. We direct the Board, in its consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art. Such analysis shall clarify whether the relied upon research aids were available prior to the critical date and whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library.

Accordingly, based on the foregoing, it is:

ORDERED that the request for POP review is denied;

FURTHER ORDERED that the original panel maintains authority over all matters, including considering the submitted rehearing request in view of the complete record; and

FURTHER ORDERED that the Board, on rehearing, shall clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art.

IPR2021-00406

Patent 10,716,793 B2

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IPR2021-00406

Patent 10,716,793 B2

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# EXHIBIT 4



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Paper 82  
Entered: February 2, 2023

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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LIQUIDIA TECHNOLOGIES, INC.,  
Petitioner,

v.

UNITED THERAPEUTICS CORPORATION,  
Patent Owner.

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IPR2021-00406  
Patent 10,716,793 B2

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Before ERICA A. FRANKLIN, CHRISTOPHER M. KAISER,  
and DAVID COTTA, *Administrative Patent Judges*.

KAISER, *Administrative Patent Judge*.

DECISION

Denying Patent Owner's Request on Rehearing of Final Written Decision  
*37 C.F.R. § 42.71(d)*

IPR2021-00406  
Patent 10,716,793 B2

## INTRODUCTION

Liquidia Technologies, Inc. (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting an *inter partes* review of claims 1–8 of U.S. Patent No. 10,716,793 B2 (Ex. 1001, “the ’793 patent”). United Therapeutics Corporation (“Patent Owner”) filed a Preliminary Response. Paper 13 (“Prelim. Resp.”).

On August 11, 2021, we instituted *inter partes* review of claims 1–8 of the ’793 patent on all grounds set forth in the Petition. Paper 18 (“Inst. Dec.”). After institution of trial, Patent Owner filed a Response (Paper 29, “PO Resp.”), Petitioner filed a Reply (Paper 44), and Patent Owner filed a Sur-Reply (Paper 55). In addition, both parties filed Motions to Exclude Evidence (Papers 65 and 66), Oppositions to their respective opponents’ Motions to Exclude (Papers 68 and 69), and Replies in support of their own Motions to Exclude (Papers 71 and 72). At the request of both parties, we held an oral hearing, the transcript of which was entered into the record. Paper 77 (“Tr.”).

On July 19, 2022, we issued a Final Written Decision determining that Petitioner had proven by a preponderance of evidence that all the challenged claims were unpatentable. Paper 78 (“Final Dec.”). On August 18, 2022, Patent Owner requested rehearing and filed a request that rehearing be conducted by the Precedential Opinion Panel. Paper 79 (“Req. Reh’g”); Paper 80. The request for rehearing by the Precedential Opinion Panel was denied, returning jurisdiction to us to consider the rehearing request itself. Paper 81.

For the reasons discussed below, we deny Patent Owner’s Request for Rehearing. Where the present decision differs from the Final Written

IPR2021-00406  
Patent 10,716,793 B2

Decision, the present decision controls. Otherwise, the Final Written Decision remains in force.

## ANALYSIS

### *A. The Final Written Decision*

Petitioner asserted the unpatentability of the challenged claims on six separate grounds. Final Dec. 3–4. Four of those grounds relied on references referred to as Voswinckel 2006 and Ghofrani, both of which we determined did not qualify as prior art. *Id.* at 3–4, 36–41. The remaining two grounds both relied on a reference referred to as Voswinckel JESC, and one of the grounds also relied on a reference referred to as Voswinckel JAHA. *Id.* at 3.

Patent Owner argued during the trial that Petitioner had not proven that either Voswinckel JESC or Voswinckel JAHA had been made publicly accessible early enough to qualify as prior art in the way that Petitioner argued they did. PO Resp. 11–18; Sur-Reply 2–11. Petitioner countered these arguments with several arguments for the public accessibility of Voswinckel JESC and Voswinckel JAHA. Reply 2–9. In particular, Petitioner argued that each of these references was cited in a publicly available journal article that could have served as a research aid to help a person of ordinary skill in the art locate the references. *Id.* at 3–4 (arguing that Voswinckel JESC was cited in Ghofrani), 7–8 (arguing that Voswinckel JAHA was cited in Sulica).

In the Final Written Decision, we were persuaded by Petitioner’s argument regarding these research aids. Final Dec. 10–12. Based in part on our determination that these research aids established the public accessibility of Voswinckel JESC and Voswinckel JAHA, we determined that Petitioner

IPR2021-00406  
Patent 10,716,793 B2

had proven by a preponderance of the evidence that each of the challenged claims would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. *Id.* at 12–35.

*B. The Rehearing Request*

Patent Owner seeks rehearing of our Final Written Decision on the ground that we overlooked Patent Owner’s argument that the Ghofrani and Sulica research aids had been “published *after* the critical §102(b) date of May 15, 2005.” Req. Reh’g 1 (emphasis in original). Patent Owner notes that this argument appeared in the Sur-Reply. *Id.* at 5 (citing Sur-Reply 9). According to Patent Owner, had we not overlooked this argument, we would have determined that Petitioner had not shown that Voswinckel JESC and Voswinckel JAHA were publicly accessible in the way necessary to treat them as prior art to the '793 patent. *Id.* at 5–14.

When it requested rehearing, Patent Owner also requested that the rehearing be conducted by the Precedential Opinion Panel. Ex. 3003. The Precedential Opinion Panel denied that request and directed us to consider Patent Owner’s rehearing request. Paper 81, 3. The Precedential Opinion Panel directed us, “in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art” and specified that “[s]uch analysis shall clarify whether the relied upon research aids were available prior to the critical date and whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library.” *Id.*

IPR2021-00406  
Patent 10,716,793 B2

### *C. Standard of Review*

A request for rehearing of an institution decision is reviewed under the abuse of discretion standard. 37 C.F.R. § 42.71(c). “The burden of showing a decision should be modified lies with the party challenging the decision.” 37 C.F.R. § 42.71(d). “The request must specifically identify all matters the party believes the Board misapprehended or overlooked, and the place where each matter was previously addressed in a motion, an opposition, reply, or a sur-reply.” *Id.* An abuse of discretion may be found where a decision “(1) is clearly unreasonable, arbitrary, or fanciful; (2) is based on an erroneous conclusion of law; (3) rests on clearly erroneous fact findings; or (4) involves a record that contains no evidence on which the Board could rationally base its decision.” *Redline Detection, LLC v. Star Envirotech, Inc.*, 811 F.3d 435, 442 (Fed. Cir. 2015) (quoting *Abrutyn v. Giovannello*, 15 F.3d 1048, 1050–51 (Fed. Cir. 1994) (citation omitted)).

### *D. We Overlooked Patent Owner’s Argument*

Patent Owner is correct that its argument that the Ghofrani and Sulica research aids were dated after May 15, 2005, appeared in the Sur-Reply. Sur-Reply 9–11. Patent Owner also is correct that we overlooked this argument in relying on these research aids as supporting that Petitioner had established that Voswinckel JESC and Voswinckel JAHA were prior art to the ’793 patent. Final Dec. 11–12; Paper 81, 2 (“the Board’s analysis did not consider whether the research aids themselves were available prior to the critical date”).

IPR2021-00406  
Patent 10,716,793 B2

*E. Reconsideration of the Record Shows that the Research Aids Did Not Establish the Prior-Art Status of Voswinckel JESC and Voswinckel JAHA*

Petitioner argued that Voswinckel JESC and Voswinckel JAHA were “prior art to the ’793 Patent under at least 35 U.S.C. § 102(b).” Pet. 22, 24. In the Final Written Decision, we determined that Petitioner had shown that these references were prior art based on the existence of research aids. Final Dec. 10–12. As noted above, that determination overlooked Patent Owner’s argument that the research aids themselves were published too late for their mention of Voswinckel JESC and Voswinckel JAHA to render those references prior art under § 102(b). We now consider that argument.

To qualify as prior art under § 102(b), a reference must have been publicly accessible “more than one year prior to the date of application for patent in the United States.” 35 U.S.C. § 102(b) (2006). Here, the parties agree that the application that ultimately led to the issuance of the ’793 patent was filed May 15, 2006. Pet. 12; PO Resp. 5. Thus, to qualify as § 102(b) prior art, Voswinckel JESC and Voswinckel JAHA must have been publicly accessible before May 15, 2005.

Petitioner argues that Voswinckel JESC “was cited in the June 2005 Ghofrani article in the journal *Herz* . . . , an article that was publicly accessible.” Reply 3 (citing Ex. 1010, 298, 301). Patent Owner argues that “Ghofrani bears a July 2005 date-stamp.” Sur-Reply 9 (citing Ex. 1121, 1). Petitioner does not explain its characterization of Ghofrani as a “June 2005” article. The pages of Ghofrani cited by Petitioner do not indicate a June 2005 publication date. Ex. 1010, 298, 301. The same article appears, however, as Exhibit 1121, which bears a date of July 7, 2005. *Compare* Ex. 1010, *with* Ex. 1121. Accordingly, Patent Owner’s characterization of

IPR2021-00406  
Patent 10,716,793 B2

Ghofrani as having been published in July 2005 is better supported by the evidence of record than is Petitioner’s characterization of Ghofrani as having been published in June 2005. Even if the evidence of record supported Petitioner’s June 2005 publication date, that date is still later than May 15, 2005, so the citation of Voswinckel JESC in Ghofrani does not show that Voswinckel JESC was prior art under § 102(b).

Petitioner argues that Voswinckel JAHA “was cited by a March 2005 article authored by Roxana Sulica et al. in the *Expert Review of Cardiovascular Therapy*.” Reply 7 (citing Ex. 1104, 359). Patent Owner argues that the Sulica article “shows only the year 2005.” Sur-Reply 9 (citing Ex. 1104, 347). We agree with Patent Owner. The Sulica article bears a 2005 copyright date but otherwise does not indicate when it was published. Ex. 1104, 347. The 2005 copyright date does not support a finding that the Sulica article was published before May 15, 2005, so the citation of Voswinckel JAHA in the Sulica article does not show that Voswinckel JAHA was prior art under § 102(b).

*F. Reexamination of the Record Shows that Voswinckel JESC and Voswinckel JAHA Were Prior Art to the ’793 Patent Due to Distribution at Conferences*

The Precedential Opinion Panel directed us, “in [our] consideration on rehearing, to clearly identify whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art” and specified that “[s]uch analysis shall clarify . . . whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference or library.” Paper 81, 3. Accordingly, we consider below whether the evidence of record establishes the prior-art status of Voswinckel JESC and Voswinckel

IPR2021-00406  
Patent 10,716,793 B2

JAHA due to presentation and/or inclusion in distributed materials. We answer this question in the affirmative.

“Because there are many ways in which a reference may be disseminated to the interested public, ‘public accessibility’ has been called the touch-stone in determining whether a reference constitutes a ‘printed publication.’” *Jazz Pharm., Inc. v. Amneal Pharm., LLC*, 895 F.3d 1347, 1356 (Fed. Cir. 2018) (quoting *In re Hall*, 781 F.2d 897, 898–99 (Fed. Cir. 1986)). A reference is considered publicly accessible if it was “disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.” *Id.* at 1355–56 (citing *In re Wyer*, 655 F.2d 221, 226 (CCPA 1981)). Under at least some circumstances, a reference may be a printed publication under § 102(b) if it was “displayed to the public,” even if it “was not later indexed in any database, catalog, or library.” *In re Klopfenstein*, 380 F.3d 1345, 1350 (Fed. Cir. 2004). There are several factors relating to whether such a display is sufficient to constitute a printed publication, including “the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied.” *Id.* In addition, distribution of a reference at a professional conference may, under at least some circumstances, constitute sufficient dissemination to show public accessibility. *Nobel Biocare Services AG v. Intradent USA, Inc.*, 903 F.3d 1365, 1375–80 (Fed. Cir. 2018); *Medtronic, Inc. v. Barry*, 891 F.3d 1368, 1380–83 (Fed. Cir. 2018).



IPR2021-00406  
Patent 10,716,793 B2

1. *Voswinckel JESC Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

A reference may be “[a] printed publication ‘ . . . if it was sufficiently disseminated at the time of its publication.’” *Medtronic*, 891 F.3d at 1381 (quoting *Suffolk Techs., LLC v. AOL Inc.*, 752 F.3d 1358, 1365 (Fed. Cir. 2014)). Several factors are relevant to the determination of whether distribution of a reference at a conference constitutes such sufficient dissemination. *Id.* at 1381–82. These include “the size and nature of the meetings and whether they are open to people interested in the subject matter of the material disclosed,” as well as “whether there is an expectation of confidentiality between the distributor and the recipients of the materials.” *Id.* at 1382. “The expertise of the target audience can [also] be a factor in determining public accessibility.” *Id.* To the extent that these factors are addressed via testimonial evidence, corroboration of that evidence may be necessary. *Nobel Biocare*, 903 F.3d at 1377–78. “Corroborating evidence may include documentary or testimonial evidence,” and “[c]ircumstantial evidence can be sufficient corroboration.” *Id.* (citing *TransWeb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1301 (Fed. Cir. 2016)).

Voswinckel JESC is an abstract contained in “Volume 25 Abstract Supplement August/September 2004” of “European Heart Journal,” with a subtitle indicating that the journal is the “Journal of the European Society of Cardiology” and that the supplement relates to “ESC Congress 2004,” held “28 August – 1 September” in “Munich, Germany.” Ex. 1007, 1; *see also* Ex. 1089, 1. The Table of Contents organizes abstracts into categories, including “Epidemiology and treatment of pulmonary arterial hypertension,” with each category associated with an entry corresponding to a day of the

IPR2021-00406  
Patent 10,716,793 B2

conference, such as “Day 2—Sunday 29 August 2004.” *Id.* at 2. Each of these categories points to a page or pages in the supplement, with those pages containing abstracts that report the “Background,” “Methods,” “Results,” and “Conclusion” of studies. *Id.* at 7.

The conference with which Voswinckel JESC is associated “is the largest medical congress in Europe and among the top three cardiology meetings in the world,” and “it has become an established forum for the exchange of science as much as education.” Ex. 1105, 19. Attendees of the conference include “basic scientists, nurses and allied professionals working in the field of cardiovascular care of patients.” *Id.* At the 2004 conference, there were “24,527 attendees,” including “18,413 professionals, 4,715 exhibitors, 636 journalists and 763 accompanying persons.” *Id.* Both Petitioner’s declarant, Dr. Nicholas Hill, and Patent Owner’s declarant, Dr. Aaron Waxman, testify that anyone who paid to attend the ESC Congress 2004 would have received a copy of the abstract book from which Voswinckel JESC is excerpted, either at the meeting itself or as a distribution before the meeting. Ex. 1106 ¶ 28; Ex. 1108, 105:16–108:1.

Thus, the evidence of record shows that Voswinckel JESC was distributed to more than twenty thousand people before or at the time of the ESC Congress 2004 in late August and early September of 2004. Those twenty thousand recipients included both highly skilled professionals, including scientists, nurses, and other clinicians, as well as journalists and those who accompanied the professionals and the journalists. That the recipients included journalists and “accompanying persons” suggests very strongly that there was no expectation that the contents of Voswinckel JESC would be kept confidential. Moreover, Drs. Hill and Waxman corroborate

IPR2021-00406  
Patent 10,716,793 B2

one another's testimony, and their testimony is further corroborated by the contents of both Voswinckel JESC itself and Exhibit 1105. The distribution of Voswinckel JESC to over twenty thousand recipients, including thousands of experts in the field of cardiology, with no expectation of confidentiality, establishes that Voswinckel JESC was a printed publication as of the date of the conference at which that distribution occurred. Because that conference occurred in August and September 2004, more than one year before the May 15, 2006 application date of the '793 patent, Voswinckel JESC was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

2. *Voswinckel JAHA Was Sufficiently Distributed at a Conference to be Publicly Accessible as of the Conference Date*

Like Voswinckel JESC, Voswinckel JAHA is associated with a professional conference. Ex. 1008. It is an abstract that has been extracted from a document headed "Supplement to Circulation," subtitled "Journal of the American Heart Association" and "Abstracts from Scientific Sessions 2004," indicating that those sessions occurred "November 7–10." *Id.* at 1. The abstract in question appears in a section titled "Pulmonary Arterial Hypertension: New Therapies," subtitled "Subspecialty: Integrative Biology" and indicating that the session occurred on "Wednesday" in "Hall I2" of the "Ernest N Morial Convention Center." *Id.* at 3. We take official notice that the range of dates from November 7, 2004, to November 10, 2004, includes Wednesday, November 10, 2004.

Both Dr. Hill and Dr. Waxman agree that attendance at the Scientific Sessions 2004 conference was large. Ex. 1106 ¶ 22 ("a [person of ordinary skill in the art] would have attended the Scientific Sessions 2004

IPR2021-00406  
Patent 10,716,793 B2

Conference, as it is one of the principal conferences on the circulatory system and diseases and conditions affecting circulation”); Ex. 1108, 116:4–21 (testifying that attendance at Scientific Sessions 2004 was likely larger than the 18,000 professionals who attended ESC Congress 2004). Dr. Hill testifies that the conference was “attended by physicians and researchers working on and studying the cardiovascular system, including pulmonary circulation.” *Id.* Both Dr. Hill and Dr. Waxman also agree that a copy of the abstract book from which Voswinckel JAHA is excerpted would have been provided to all attendees at Scientific Sessions 2004. Ex. 1106 ¶ 23; Ex. 1108, 108:3–20. We have not been directed to any evidence of record indicating there was any expectation of confidentiality. The distribution of thousands of copies of Voswinckel JAHA at the conference is strong evidence that Voswinckel JAHA was a printed publication as of the date of the conference. Because that conference occurred in November 2004, more than one year before the May 15, 2006 application date of the ’793 patent, Voswinckel JAHA was a printed publication early enough to qualify as prior art under 35 U.S.C. § 102(b).

### 3. *Conclusion*

As instructed by the Precedential Opinion Panel, we have considered “whether the Voswinckel JESC and Voswinckel JAHA references qualify as prior art” and in particular “whether the Voswinckel JESC and Voswinckel JAHA references were publicly accessible by way of their presentation and/or inclusion in distributed materials, such as at a conference.” Paper 81, 3. As discussed above, we find that both references were distributed sufficiently at professional conferences to be publicly accessible at the time of those conferences. By virtue of this public accessibility, both Voswinckel

IPR2021-00406  
Patent 10,716,793 B2

JESC and Voswinckel JAHA were printed publications early enough to qualify as prior art under 35 U.S.C. § 102(b).

*G. Asserted Obviousness over '212 Patent, Voswinckel JESC, and Voswinckel JAHA*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA. Pet. 30–46. As discussed above, Petitioner has shown by a preponderance of the evidence that both Voswinckel JESC or Voswinckel JAHA qualify as prior art. Accordingly, we do not disturb the obviousness analysis in the Final Written Decision, which relies on the prior-art status of Voswinckel JESC and Voswinckel JAHA. Final Dec. 12–35.

*H. Remaining Grounds*

Petitioner argues that claims 1–8 would have been obvious over the combination of the '212 patent and Voswinckel JESC. Pet. 46–50. We do not disturb the determination in the Final Written Decision that we need not reach this ground “[b]ecause Petitioner has shown by a preponderance of the evidence that all of the challenged claims would have been obvious over the similar combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.” Final Dec. 36.

Petitioner argues that claim 1 was anticipated by Ghofrani; that claims 1, 3, and 8 would have been obvious over the combination of Voswinckel JAHA and Ghofrani; that claims 1 and 3 were anticipated by Voswinckel 2006; and that claims 2 and 4–8 would have been obvious over the combination of Voswinckel 2006 and the '212 patent. Pet. 50–64. These grounds fail for the reasons discussed in the Final Written Decision. Final Dec. 36–41.

For the reasons discussed above, Patent Owner has shown that we overlooked its argument regarding the date of availability of the research aids that Petitioner argued showed that Voswinckel JESC and Voswinckel JAHA qualified as prior art. A proper consideration of that argument shows that the research aids do not establish the prior-art status of Voswinckel JESC and Voswinckel JAHA, but there is no change to the outcome with respect to Petitioner's asserted grounds of unpatentability, because the distribution of Voswinckel JESC and Voswinckel JAHA at professional conferences proves the prior-art status of those references. Accordingly, we deny Patent Owner's request for rehearing.

Outcome of Decision on Rehearing:

Claims	35 U.S.C §	Reference(s)/Basis	Denied	Granted
1–8	103(a)	'212 patent, Voswinckel JESC, Voswinckel JAHA	1–8	
<b>Overall Outcome</b>			1–8	

14

IPR2021-00406  
Patent 10,716,793 B2

Final Outcome of Final Written Decision after Rehearing:

<b>Claims</b>	<b>35 U.S.C. §</b>	<b>Reference(s)/Basis</b>	<b>Claims Shown Unpatentable</b>	<b>Claims Not Shown Unpatentable</b>
1–8	103(a)	'212 patent, Voswinckel JESC, Voswinckel JAHA	1–8	
1–8	103(a)	'212 patent, Voswinckel JESC <sup>2</sup>		
1	102(a)	Ghofrani		1
1, 3, 8	103(a)	Voswinckel JAHA, Ghofrani		1, 3, 8
1, 3	102(a)	Voswinckel 2006		1, 3
2, 4–8	103(a)	Voswinckel 2006, '212 patent		2, 4–8
<b>Overall Outcome</b>			1–8	

ORDER

It is hereby

ORDERED that Patent Owner's Request for Rehearing is denied;

FURTHER ORDERED that the determination in the Final Written Decision that the research aids relied on by Petitioner show the prior-art status of Voswinckel JESC and Voswinckel JAHA is overturned and replaced with the determination in the present decision that the distribution

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<sup>2</sup> Neither the Final Written Decision nor this Rehearing Decision reaches this ground because Petitioner has proven all challenged claims are unpatentable based on obviousness over the combination of the '212 patent, Voswinckel JESC, and Voswinckel JAHA.

IPR2021-00406  
Patent 10,716,793 B2

of Voswinckel JESC and Voswinckel JAHA at professional conferences establishes the prior-art status of those references;

FURTHER ORDERED that, based on the preponderance of the evidence, claims 1–8 of the '793 patent have been shown to be unpatentable;

FURTHER ORDERED that all other rulings in the Final Written Decision remain undisturbed; and

FURTHER ORDERED that parties to this proceeding seeking judicial review of this Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.



IPR2021-00406  
Patent 10,716,793 B2

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IPR2021-00406  
Patent 10,716,793 B2

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS  
CORPORATION,

Plaintiff,

V.

LIQUIDIA TECHNOLOGIES, INC.,

Defendant.

C.A. No. 20-755 (RGA) (JLH)

**UTC’S ANSWERING BRIEF IN OPPOSITION TO  
LIQUIDIA’S MOTION FOR POST JUDGMENT RELIEF PURSUANT TO  
FEDERAL RULE OF CIVIL PROCEDURE 60(B)**

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January 16, 2024

# TABLE OF CONTENTS

I.	INTRODUCTION .....	1
II.	NATURE AND STAGE OF PROCEEDINGS AND STATEMENT OF FACTS .....	1
III.	SUMMARY OF ARGUMENT .....	3
IV.	ARGUMENT .....	4
A.	Legal Standards.....	4
B.	Under Third Circuit Law, the Consequences of Liquidia’s Strategic Decision to Pursue an IPR Cannot Support Modifying this Court’s Final Judgment.....	5
C.	Liquidia’s Motion Is Premature Because the PTO Has Not Canceled the Claims of the ’793 Patent.....	6
D.	Liquidia Is Not Entitled to Relief from this Court’s Final Judgment Under Rules 60(b)(5) or 60(b)(6) .....	10
V.	CONCLUSION .....	14

## TABLE OF AUTHORITIES

<b>Cases</b>	<b>Page(s)</b>
<i>Bajaj v. Fisher Asset Mgmt., LLC</i> , C.A. No. 11-286-RGA, 2013 WL 12443155 (D. Del. Feb. 11, 2013) .....	11
<i>Bldg. &amp; Const. Trades Council of Philadelphia &amp; Vicinity, AFL-CIO v. N.L.R.B.</i> , 64 F.3d 880 (3d Cir. 1995).....	5, 10, 11
<i>Boughner v. Sec’y of Health, Educ. &amp; Welfare</i> , 572 F.2d 976 (3d Cir. 1978).....	4
<i>Coltec Indus., Inc. v. Hobgood</i> , 280 F.3d 262 (3d Cir. 2002).....	4, 5, 6, 12
<i>Democratic Nat’l Comm. v. Republican Nat’l Comm.</i> , 673 F.3d 192 (3d Cir. 2012).....	5
<i>Dragon Intell. Prop., LLC v. Apple, Inc.</i> , C.A. No. 13-2058-RGA, 2018 WL 4658208 (D. Del. Sept. 27, 2018) .....	12
<i>Ehrheart v. Verizon Wireless</i> , 609 F.3d 590 (3d Cir. 2010).....	6
<i>ePlus, Inc. v. Lawson Software, Inc.</i> , 789 F.3d 1349 (Fed. Cir. 2015).....	9, 13
<i>Fresenius USA, Inc. v. Baxter Intern., Inc.</i> , 721 F.3d 1330 (Fed. Cir. 2013).....	9
<i>In re Bingo Card Minder Corp.</i> , 152 F.3d 941 (Fed. Cir. 1998).....	7
<i>In re Fine Paper Antitrust Litig.</i> , 840 F.2d 188 (3d Cir. 1988).....	5
<i>Mendenhall v. Barber-Greene Co.</i> , 26 F.3d 1573 (Fed. Cr. 1994).....	12, 13
<i>Oat v. Sewer Enterprises, Ltd.</i> , 584 F. App’x 36 (3d Cir. 2014) .....	5, 10
<i>Prism Techs. LLC v. Sprint Spectrum, L.P.</i> , 757 F. App’x 980 (Fed. Cir. 2019) .....	13
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , 74 F.4th 1360 (Fed. Cir. 2023) .....	3, 7



## **I. INTRODUCTION**

Liquidia’s Motion for Post Judgment Relief (D.I. 461, “Motion”) is premature and should be denied. On September 9, 2022, this Court entered final judgment in favor of United Therapeutics (“UTC”) after finding U.S. Patent No. 10,716,793 (“the ’793 patent”) to be infringed and not invalid, a determination that the Federal Circuit affirmed. Liquidia now seeks to undo that final judgment based on pending *Inter Partes* Review (“IPR”) proceedings. Those IPR proceedings involve invalidity arguments Liquidia abandoned in this action prior to trial. It was Liquidia—not UTC—that decided to litigate the validity of the ’793 patent in two separate forums on two separate timelines with differing legal standards. Liquidia must abide by the consequences of its decision: the final judgment bars Liquidia from obtaining final approval until the earlier of the ’793 patent’s expiration or cancelation of the claims under 35 U.S.C. § 318(b).

Critically, while Liquidia has to this point prevailed in its IPR challenge, those proceedings are not yet complete and UTC has not yet exhausted its appellate rights. The claims of the ’793 patent therefore have not been canceled—and will not be canceled—until any appeals of the IPR decision have terminated. In contrast, the Federal Circuit has issued its mandate to this Court—affirming this Court’s final judgment, including the statutory relief granted to UTC. There is no basis in law or equity to disturb that final judgment while the claims of the ’793 patent remain in force. The Court should reject Liquidia’s request to do so.

## **II. NATURE AND STAGE OF PROCEEDINGS AND STATEMENT OF FACTS**

In April 2020, Liquidia notified UTC that it had submitted NDA No. 213005 (“Liquidia’s 505(b)(2) Application”) to the FDA seeking approval to market LIQ861, a proposed product relying on information contained in UTC’s NDA No. 022387 for its innovative drug product TYVASO® (treprostinil) Inhalation Solution. Shortly thereafter, UTC sued Liquidia alleging infringement of certain patents, including the ’793 patent, listed in the Orange Book in connection



with TYVASO®. D.I. 16. Liquidia asserted counterclaims on August 5, 2020, alleging, *inter alia*, that the asserted claims of the '793 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and 112. D.I. 23 at 17. Five months later, on January 7, 2021, Liquidia filed an IPR petition against the '793 patent, presenting the same anticipation and obvious grounds as it presented in this action.

This Court conducted a four-day bench trial from March 28-31, 2022. Liquidia decided not to present any of its anticipation or obviousness arguments for the '793 patent at trial, despite litigating them all the way through the final pretrial order. On July 19, 2022, the PTAB issued a Final Written Decision in the parallel IPR proceeding finding all challenged claims of the '793 patent unpatentable. D.I. 452-1 at 2. In subsequent briefing, Liquidia requested that this Court stay its decision on the '793 patent pending appeal of the IPR decision. D.I. 427 at 3. This Court denied Liquidia's request on August 30, 2022. D.I. 432.

On August 31, 2022, this Court issued its opinion finding that the asserted claims of the '793 patent are not invalid and would be infringed by LIQ861. D.I. 433 at 53. This Court found that the LIQ861 label would induce infringement of the asserted claims of the '793 patent. *Id.* at 35. This Court also found that the '793 patent is enabled and discloses every element of the asserted claims, and thus that the '793 patent is not invalid on any of the grounds Liquidia argued before this Court. *Id.* at 44. Final judgment for the purposes of appeal was entered on September 9, 2022. D.I. 436. Liquidia subsequently moved to stay enforcement of paragraph 4 of the final judgment, the non-discretionary statutory remedy ordering FDA not to approve Liquidia's 505(b)(2) Application until the expiration of the '793 patent. D.I. 438. Briefing on Liquidia's motion to stay was filed in September 2022, and this Court reserved decision. D.I. 439; D.I. 442; D.I. 444.

Nine months later, on July 24, 2023, the Federal Circuit affirmed this Court’s decision that the asserted claims of the ’793 patent are not invalid and would be infringed by Liquidia’s product. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1363 (Fed. Cir. 2023). The mandate of the Federal Circuit issued to this Court on October 3, 2023. D.I. 453.

On November 9, 2023, this Court ordered further briefing on Liquidia’s motion to stay (D.I. 438) in light of the Federal Circuit’s affirmance and mandate. D.I. 457. This Court ultimately denied Liquidia’s motion because Liquidia failed to show a likelihood of success on the merits in the IPR proceeding, which was—and is—still on appeal. D.I. 460 at 3. This Court reasoned that it was “unfamiliar with the record and the issues” in the IPR proceeding and that it “had no basis on which to evaluate the likelihood of success of Liquidia’s appeal.” *Id.*

On December 15, 2023, a panel of the Federal Circuit affirmed the PTAB’s judgment in the IPR proceeding. *United Therapeutics Corp. v. Liquidia Techs. Inc.*, No. 2023-1805, 2023 WL 8794633 (Fed. Cir. Dec. 20, 2023). Liquidia filed the instant motion on December 26, 2023. D.I. 461. The appellate proceedings are not yet final because, as Liquidia correctly stated in its briefing, UTC “intends to seek rehearing by the Federal Circuit” (D.I. 462 at 5), and if UTC does not prevail, it has the option to seek Supreme Court review. To date, the Federal Circuit has yet to issue a mandate in the appeal of the IPR and the Patent and Trademark Office (“PTO”) has not canceled the infringed claims of the ’793 patent. UTC’s deadline to request panel and *en banc* rehearing of the Federal Circuit’s decision is currently January 19, 2024.

### **III. SUMMARY OF ARGUMENT**

A pending IPR proceeding cannot override this Court’s final judgment, which grants a mandatory statutory remedy. While this case has a final judgment, an affirmance on appeal, and a mandate from the Federal Circuit, the IPR appeal remains pending with upcoming motions for rehearing and no issued mandate. Liquidia’s Motion is therefore premature and should be denied.

The claims of the '793 patent remain in force because of Liquidia's own strategic decision to pursue parallel IPR proceedings that have not yet concluded. Liquidia's Motion fails to mention that a certificate of cancellation has not issued as to the '793 patent, and it is only then (if ever) that claims of the '793 patent would be canceled. Binding and persuasive precedent supports maintaining a final judgment unless and until the claims of the '793 patent are canceled by the certificate prescribed by statute, 35 U.S.C. § 318(b). To the extent that this Court believes it appropriate to weigh the equities in determining whether to grant Liquidia's Motion, final judgments should not be disturbed lightly, and Liquidia has failed to show that it is entitled to relief under Rules 60(b)(5) or 60(b)(6). Liquidia's contrary arguments are meritless and internally contradictory. Liquidia's Motion should be denied.

#### **IV. ARGUMENT**

##### **A. Legal Standards**

Third Circuit law governs Liquidia's Motion. *W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558, 561 n.3 (Fed. Cir. 1992). In patent cases, the Federal Circuit has also been guided by its own precedent in assessing whether to disrupt judgments obtained in asserting a later-invalidated patent. *WesternGeco L.L.C. v. ION Geophysical Corp.*, 913 F.3d 1067, 1072 (Fed. Cir. 2019).

Liquidia bases its Motion on two provisions of the same rule: Federal Rule of Civil Procedure 60(b)(5) and 60(b)(6). D.I. 462 at 2. "The general purpose of Rule 60(b) . . . is to strike a proper balance between the conflicting principles that litigation must be brought to an end and that justice must be done." *Coltec Indus., Inc. v. Hobgood*, 280 F.3d 262, 271 (3d Cir. 2002) (quoting *Boughner v. Sec'y of Health, Educ. & Welfare*, 572 F.2d 976, 977 (3d Cir. 1978) (alteration in *Coltec*)). To the extent that equitable concerns are relevant in this procedural posture,

Liquidia bears a “heavy burden” of establishing an equitable right to relief. *E.g., Oat v. Sewer Enterprises, Ltd.*, 584 F. App’x 36, 41 (3d Cir. 2014) (non-precedential).

This case involves a statutory form of relief, not a discretionary equitable injunction. When determining whether to vacate an equitable injunction under Rule 60(b)(5) on the ground that applying it prospectively is “no longer equitable,” the Third Circuit rejects “a rigid, pervasively applicable rule.” *Bldg. & Const. Trades Council of Philadelphia & Vicinity, AFL-CIO v. N.L.R.B.*, 64 F.3d 880, 888 (3d Cir. 1995) (“*BCTC*”). Instead, the Court must consider:

[T]he circumstances leading to entry of the injunction and the nature of the conduct sought to be prevented; the length of time since entry of the injunction; whether the party subject to its terms has complied or attempted to comply in good faith with the injunction; and the likelihood that the conduct or conditions sought to be prevented will recur absent the injunction. . . . Courts which have faced similar issues also have identified as a relevant factor whether the conduct previously enjoined has become legal due to a change in the law.

*Id.*; see also *Democratic Nat’l Comm. v. Republican Nat’l Comm.*, 673 F.3d 192, 202 (3d Cir. 2012).

In contrast, “the Rule 60(b)(6) ground for relief from judgment provides for extraordinary relief and may only be invoked upon a showing of exceptional circumstances.” *Coltec*, 280 F.3d at 273 (quoting *In re Fine Paper Antitrust Litig.*, 840 F.2d 188, 194 (3d Cir. 1988)). In particular, the Third Circuit rejects Rule 60(b)(6) relief where a party seeks to undo its own voluntary litigation decision that “was improvident in hindsight.” *Coltec*, 280 F.3d at 275.

**B. Under Third Circuit Law, the Consequences of Liquidia’s Strategic Decision to Pursue an IPR Cannot Support Modifying this Court’s Final Judgment**

Liquidia argues that it would be “manifest injustice” if this Court refused to treat the Federal Circuit panel’s decision in the IPR appeal as the last word and modify the final judgment in this action on that basis. D.I. 462 at 8. But in this case, unlike in the cases on which Liquidia relies (*see infra* § IV.D), the purported “injustice” Liquidia seeks to prevent is a problem of its

own making. And the Third Circuit has found strategic litigation “decisions, when voluntarily made, to be calculated and deliberate choices by a litigant, choices which provide no relief when the legal landscape subsequently changes.” *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 595 (3d Cir. 2010) (citing *Coltec*, 280 F.3d at 274–75).

The ’793 patent IPR was Liquidia’s voluntary, calculated, and deliberate choice. Liquidia alone chose to split its validity defenses between this Court and the PTAB rather than litigating all its invalidity arguments together before this Court. When it decided to pursue its prior-art challenges outside of this Court in IPR proceedings, Liquidia selected a proceeding governed by a separate statutory scheme and run on an independent schedule. Liquidia opted for a lighter burden of proof, *compare* 35 U.S.C. § 315(e) (preponderance standard for IPRs) *with* D.I. 433 at 37 (clear-and-convincing standard in district court), but in exchange it had to adhere to the IPR process’s statutory timeline. As discussed in detail below, under these statutes and regulations, only if Liquidia prevails at the end of the IPR proceedings and the PTO cancels the claims of the ’793 patent would there be any basis to disturb this Court’s final and affirmed judgment. *See infra* § IV.C.–D. This Court should not grant Liquidia an improper procedural shortcut that would allow it to reap the benefit of its strategic choice while dodging the strategic cost. Rather, Liquidia must accept the procedural consequences of its choice and abide by the statutes and regulations governing the IPR process it selected: unless and until the patent claims are canceled, the ’793 patent is still in force, and Liquidia’s Motion is premature.

### **C. Liquidia’s Motion Is Premature Because the PTO Has Not Canceled the Claims of the ’793 Patent**

Liquidia repeatedly asserts that the Federal Circuit panel’s recent affirmance of the PTAB’s IPR decision should be taken as the final word on the validity of the ’793 patent. *See generally* D.I. 462 at 5–8. This, however, ignores the statutory regime. The IPR process is not yet complete

Indeed, the Federal Circuit has already explained in this very case that “the Board’s final written decision does not cancel claims; the claims are canceled when the Director issues a certificate confirming unpatentability, which occurs only after ‘the time for appeal has expired or any appeal has terminated.’” *United Therapeutics*, 74 F.4th at 1372 (quoting 35 U.S.C. § 318). This principle has been part of the administrative review of issued patents for decades. *See, e.g., In re Bingo Card Minder Corp.*, 152 F.3d 941, at \*2 (Fed. Cir. 1998) (non-precedential) (“A claim is not canceled until the Board acts and the Commissioner cancels the claim. Because the Commissioner has not yet issued a certificate canceling the claims, they have not been finally determined to be unpatentable.”). Congress understood that history when it enacted the statute governing IPRs.

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discretionary injunction imposed by this Court’s judgment pursuant to 35 U.S.C. § 271(e)(4)(A) should not be lifted unless and until the ’793 patent is actually canceled.

That the ’793 patent remains in force is fatal to Liquidia’s Motion—and the authority Liquidia cites demonstrates as much. The statutory order precluding FDA approval that Liquidia seeks to set aside, *see* D.I. 436 ¶ 4, is based on the duly-issued ’793 patent and this Court’s finding that Liquidia’s product would infringe it (and that Liquidia failed to prove invalidity in this case). Unless and until the claims of that patent are canceled, the legal basis for the remedy remains. Not once but twice, Liquidia argues the contrary by citing *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1354–55 (Fed. Cir. 2015), for the proposition that “an injunction must be set aside when the legal basis for it has ceased to exist.” D.I. 462 at 5, 7. But the final judgment does not include an equitable injunction but relief prescribed by statute. Moreover, in *ePlus*, the Federal Circuit repeated over and over that it was “[t]he PTO’s cancellation of claim 26” that “require[d] that we now vacate the injunction.” 789 F.3d at 1356, 1361; *see id.* at 1351, 1354, 1356, 1358, 1361 (similar). It was not the reexamination decision by the PTAB’s predecessor, nor was it the Federal Circuit’s panel decision affirming, nor even issuance of the Federal Circuit’s mandate. *Id.* Likewise, in *Fresenius USA, Inc. v. Baxter Intern., Inc.*, 721 F.3d 1330 (Fed. Cir. 2013), the court repeatedly emphasized that it was the PTO’s cancellation of the relevant claims, after reexamination and appeal, that required a judgment awarding damages on the same claims to be set aside on appeal. *See id.* at 1332, 1335, 1336, 1338, 1339, 1340. Liquidia’s Motion is premature, and relief from judgment is not warranted while the IPR process remains ongoing.

Finally, Liquidia asks this Court to treat its judgment in this case as not final, despite the denied rehearing requests and mandate, because of Liquidia’s own potential petition for certiorari. This position, however, directly contradicts its other assertion that UTC’s IPR appeal is final



notwithstanding UTC's forthcoming petition for rehearing and the lack of any mandate. Liquidia's self-contradictory positions belie its arguments, and in fact the reality is the opposite: this Court's judgment is final while the appeal-still-pending IPR is not. Liquidia's argument is inherently flawed and should be rejected. Under the IPR statute, the '793 patent cannot be canceled until after UTC has an opportunity to petition for rehearing, the Federal Circuit issues its mandate, and all appeals terminate.

**D. Liquidia Is Not Entitled to Relief from this Court's Final Judgment Under Rules 60(b)(5) or 60(b)(6)**

As discussed above, Liquidia's Motion is premature and should be denied. However, to the extent that this Court determines Liquidia's motion should be considered at all, Liquidia bears the burden of showing it is entitled to relief from a final judgment, but has not—and indeed cannot—carry that burden here. *See Oat*, 584 F. App'x at 41. The relief this Court awarded is not a discretionary equitable remedy; it is the statutorily required remedy so long as the patent remains in force. *See supra* § IV.C. But even if this case involved a discretionary injunction under the Court's equitable power, no modification would be warranted at this time.

As noted above, the Third Circuit has instructed courts to consider a number of factors in addressing 60(b)(5) motions seeking to modify an injunction including “the circumstances leading to entry of the injunction and the nature of the conduct sought to be prevented; the length of time since entry of the injunction; whether the party subject to its terms has complied or attempted to comply in good faith with the injunction; and the likelihood that the conduct or conditions sought to be prevented will recur absent the injunction” as well as “whether the conduct previously enjoined has become legal due to a change in the law.” *BCTC*, 64 F.3d at 888. None of those factors justify upending the final judgment that the Court entered.

At this point, there has been no relevant change in law that would allow Liquidia to engage in otherwise-infringing conduct. 35 U.S.C. § 318. As explained above, until the PTO cancels the claims, Liquidia’s requested relief would disrupt UTC’s independent rights under this Court’s final judgment. Similarly, “the circumstances leading to entry of the injunction,” including Liquidia’s own decision to delay in bringing its IPR petition, its decision not to present anticipation and obviousness arguments at trial, and its subsequent loss at trial, all support denial of Liquidia’s Motion. *BCTC*, 64 F.3d at 888.

The Federal Circuit has recognized that “sanctity” is to be afforded to a “final judgment” in patent cases. *Woods v. Tsuchiya*, 754 F.2d 1571, 1582 (Fed. Cir. 1985). That accords with the general rule that “[a] valid and final personal judgment is conclusive between the parties, except on appeal or other direct review . . . .” *Restatement (Second) of Judgments* § 17 (1982). And Rule 60(b) is not “a substitute for an appeal.” *E.g., Bajaj v. Fisher Asset Mgmt., LLC*, C.A. No. 11-286-RGA, 2013 WL 12443155, at \*1 (D. Del. Feb. 11, 2013). This Court’s final judgment, resolving the infringement and invalidity questions before it, has been affirmed by the Federal Circuit and should not be revisited in this Court unless and until the PTO takes action to cancel any claims. *See W.L. Gore & Assocs., Inc. v. C.R. Bard, Inc.*, 977 F.2d 558, 560 (Fed. Cir. 1992) (“[p]ublic policy dictates that there be an end of litigation; that those who have contested an issue shall be bound by the result of the contest, and that matters once tried shall be considered forever settled as between the parties.”) (cleaned up). Equity requires no other outcome: Liquidia’s own strategic decisions created this situation and UTC would be prejudiced by granting Liquidia’s motion before the ’793 patent is canceled.

The Federal Circuit’s recent decision in *WesternGeco*, 913 F.3d at 1071, is instructive. There, the Federal Circuit considered a motion for relief from a money judgment where a patent

Finally, Liquidia's Motion relies on precedent in which two cases were actually pending before the Federal Circuit at the same time, so that an affirmance in one had an issue-preclusive effect on the other. D.I. 462 at 5 (citing *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282, 1295 (Fed. Cir. 2018)); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994); *Dragon Intell. Prop., LLC v. Apple, Inc.*, C.A. No. 13-2058-RGA, 2018 WL 4658208, at \*2 (D. Del. Sept. 27, 2018)). Applying preclusion under those circumstances without waiting for rehearing or mandate may sometimes be understandable: if the Federal Circuit ultimately were to grant rehearing in the IPR appeal, disturbing any opinion of invalidity, it could also grant rehearing in the district court matter to undo any application of collateral estoppel. In contrast to those cases, however, the appeal from this case is no longer pending in the Federal Circuit; Liquidia lost its appeal from this Court's judgments on the '793 patent. Liquidia did not even move for (much less obtain) a stay of mandate; and the mandate affirming this Court's final judgment has issued.

Liquidia cites no case in which the Federal Circuit has treated a panel decision affirming the PTAB as having an issue-preclusive effect on cases *no longer* pending in the Federal Circuit. *See VirnetX Inc. v. Apple Inc.*, No. 6:10-CV-417, 2020 WL 10223391, at \*4 (E.D. Tex. Sept. 1, 2020) (“[T]he PTAB issued its decisions after direct review concluded in this case, making [movant’s Rule 60(b) authority] inapplicable.”). And even in Liquidia’s cited cases, the Federal Circuit has often been hesitant to apply preclusion before direct review is complete. For example, in *Mendenhall*, after hearing argument in three related cases on the same day and deciding the first one, the Federal Circuit did not decide the other two on the basis of issue preclusion until after rehearing *and* certiorari had been denied in the first case. *See* 26 F.3d at 1577.

The unpublished decision in *Prism Techs. LLC v. Sprint Spectrum, L.P.*, 757 F. App’x 980, 987 (Fed. Cir. 2019), also does not support Liquidia’s position. Significantly, *Prism* (like *Mendenhall*) did not involve a PTAB decision at all—it involved the issue-preclusive effect of litigation brought by the same patentee against another defendant. The Federal Circuit held that its own decision was “akin for present purposes to a cancellation of those claims.” *Id.* But in the IPR context, as shown above, the cancellation *itself* is the key event; there is no need to identify some other event “akin” to a cancellation. Furthermore, in *Prism* the money judgment’s “execution had been stayed” pending all appeals, which had not yet been completed. 757 F. App’x at 982. As this Court is aware, Liquidia asked this Court to stay its judgment and this Court denied that motion. D.I. 460.<sup>1</sup> Accordingly, the reasoning of these cases does not apply here. Liquidia may seek relief from judgment only if the PTO actually cancels the claims of the ’793 patent that Liquidia has been found to infringe.

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<sup>1</sup> Indeed, Liquidia itself once recognized that entry of final judgment was legally significant, but that was before Liquidia failed to obtain a stay of this Court’s judgment. *See* D.I. 458 at 2 (arguing that a stay was necessary to prevent United Therapeutics “asserting, in contrast to *ePlus* and *Mendenhall*, that the § 271(e)(4)(A) injunction cannot be lifted and must remain in effect.”).

For the reasons above, the Court should deny Liquidia's Motion for post judgment relief.



## CERTIFICATE OF SERVICE





IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 20-755-RGA  
 )  
LIQUIDIA TECHNOLOGIES, INC., )  
 )  
Defendant. )

**LIQUIDIA'S REPLY BRIEF IN SUPPORT OF MOTION FOR POST JUDGMENT  
RELIEF PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 60(B)**

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## TABLE OF CONTENTS

		<b>Page</b>
I.	THE INVALID '793 PATENT CAN NO LONGER SUPPORT ENJOINING THE FDA FROM GRANTING FINAL NDA APPROVAL OF YUTREPIA™ .....	1
A.	Liquidia's Motion Is Not Premature Because the '793 Patent Is Invalid .....	1
B.	The '793 Patent Is No Longer Enforceable .....	2
C.	Liquidia Has Satisfied the Requirements of Rule 60(b) .....	4
II.	CLAIM CANCELLATION UNDER 35 U.S.C. § 318 IS NOT REQUIRED .....	8
III.	CONCLUSION.....	10

## TABLE OF AUTHORITIES

**Page(s)**

## Cases

<i>Bladg. &amp; Const. Trades Council of Phil. &amp; Vicinity, AFL-CIO v. N.L.R.B.</i> , 64 F.3d 880 (3d Cir. 1995).....	4
<i>Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.</i> , 402 U.S. 313 (1971).....	1, 10
<i>Coltec Industries, Inc. v. Hobgood</i> , 280 F.3d 262 (3d Cir. 2002).....	6, 7
<i>Commil USA, LLC v. Cisco Sys., Inc.</i> , 575 U.S. 632 (2015).....	5
<i>ePlus, Inc. v. Lawson Software, Inc.</i> , 789 F.3d 1349 (Fed. Cir. 2015).....	1, 2, 9
<i>MaxLinear, Inc. v. CF CRESPE LLC</i> , 880 F.3d 1373, 1376 (Fed. Cir. 2018).....	10
<i>Mendenhall v. Barber-Greene Co.</i> , 26 F.3d 1573 (Fed. Cir. 1994).....	1, 2, 7, 10
<i>Prism Techs., LLC v Sprint Spectrum, L.P.</i> , 757 F. App'x 980 (Fed. Cir. 2019) .....	7
<i>Sec. People, Inc. v. Iancu</i> , 971 F.3d 1355 (Fed. Cir. 2020).....	9
<i>United States v. Swift &amp; Co.</i> , 286 U.S. 106 (1932).....	2
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , 74 F.4th 1360 (Fed. Cir. 2023) .....	2
<i>United Therapeutics Corp. v. Liquidia Techs., Inc.</i> , C.A. No. 1:23-cv-00975-RGA, D.I. 8 (D. Del. Nov. 30, 2023) .....	3
<i>WesternGeco L.L.C. v. ION Geophysical Corp.</i> , 913 F.3d 1067 (Fed. Cir. 2019).....	5
<i>Worden v. Searls</i> , 121 U.S. 14 (1887).....	4
<i>XY, LLC v. Trans Ova Genetics, L.C.</i> , 890 F.3d 1282 (Fed. Cir. 2018).....	2, 8

## TABLE OF AUTHORITIES

**Page(s)**

## Statutes

21 U.S.C. § 355(c)(3)(C)(ii)(I) .....4, 9, 10

35 U.S.C.

§ 271(e)(4)(A).....	1
§ 315(b).....	6
§ 315(e)(2) .....	6
§ 318.....	8, 9, 10
§ 318(b).....	9

## Other Authorities

21 C.F.R. § 314.107(b)(3)(iii)(A) .....9

# Federal Rule of Civil Procedure

60.....	5
60(b).....	2, 4, 6, 8
60(b)(5).....	4, 6, 8
60(b)(6).....	1, 6, 7, 8

**I. THE INVALID '793 PATENT CAN NO LONGER SUPPORT ENJOINING THE FDA FROM GRANTING FINAL NDA APPROVAL OF YUTREPIA™**

**A. Liquidia's Motion Is Not Premature Because the '793 Patent Is Invalid**

Contrary to UTC's principal argument, Liquidia's request that the Court lift the injunction based on the '793 patent that is currently blocking final FDA approval for Yutrepia™ is not premature. *See e.g.*, D.I. 465 at 1, 10. "It is well established that an injunction *must be set aside* when the legal basis for it has ceased to exist." *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1354–1355 (Fed. Cir. 2015) (emphasis added); *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1577 (Fed. Cir. 1994) (recognizing that upholding an injunction based on an invalid patent would be at odds with the court's historical treatment of patents it recently declared invalid); *see also Blonder-Tongue Lab'ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334–346 (1971) (discussing the economic policy rationale for applying collateral estoppel based on prior invalidity judgments). Here, there is no dispute between the parties that the PTAB issued a FWD invalidating all claims of the '793 patent and that the Federal Circuit affirmed that decision. D.I. 462 at 1–2; D.I. 465 at 2–3. UTC has conceded this point. *See* D.I. 465 at 3. Thus, the parties agree that the '793 patent has been found to be invalid in a decision that has collateral estoppel effect. Accordingly, and consistent with the purpose of Federal Rule of Civil Procedure 60(b)(5)–(6), because the '793 patent has been finally determined to be invalid, the legal basis for the Court's liability of infringement finding and injunction under 35 U.S.C. § 271(e)(4)(A) no longer exists, warranting relief from the Judgment.

UTC asserts that in *ePlus*, cancellation of claims was required—not so. D.I. 465 at 9. In *ePlus*, the sole patent claim that gave rise to the injunction was found invalid by the PTO in a reexamination proceeding. 789 F.3d at 1354. But when assessing whether the injunction in *ePlus* was still enforceable, the Federal Circuit stated "[A] court does not abdicate its power to revoke

or modify its mandate, if satisfied that what it has been doing has been turned through changing circumstances into an instrument of wrong.” *Id.* at 1355 (quoting *United States v. Swift & Co.*, 286 U.S. 106, 114–15 (1932)). The *ePlus* court also pointed to its earlier decision in *Mendenhall*, where the Federal Circuit determined that the injunction had to be reversed because the patent forming the basis for injunction had been finally adjudicated invalid by a different *district court*. *Id.* (citing *Mendenhall*, 26 F.3d at 1584). Indeed, in *Mendenhall*, the collateral estoppel impact necessitating reversal of the injunction “arose upon the district court’s judgment of invalidity” of the asserted claims in a different infringement suit. *Mendenhall*, 26 F.3d at 1578, n.5. That same reasoning applies here, given the Federal Circuit’s affirmance of the PTAB’s ’793 patent FWD and the immediate collateral estoppel effect that decision has. Accordingly, Liquidia’s motion is not premature and relief under Rule 60(b) can be granted.

## **B. The ’793 Patent Is No Longer Enforceable**

UTC contends that the “claims of the ’793 patent remain in force[,]” and, as such, this is “fatal” to Liquidia’s motion. D.I. 465 at 4, 9. UTC’s position is legally incorrect. As the Federal Circuit has explained, “an affirmance of an invalidity finding, whether from a district court or the Board, has a collateral estoppel effect on all pending or co-pending actions.” *XY, LLC v. Trans Ova Genetics, L.C.*, 890 F.3d 1282, 1294 (Fed. Cir. 2018).<sup>1</sup> UTC, this Court, and the Federal Circuit have all cited, with approval, *XY* for this principle. D.I. 428 at 1; D.I. 433 at 36; *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1372 (Fed. Cir. 2023). In fact, UTC

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<sup>1</sup>Liquidia does not concede that the IPR FWD itself does not have immediate preclusive effect. While this Court and the Federal Circuit have inferred such a holding in this case, for the reasons that will be presented in Liquidia’s petition for a writ of certiorari to the Supreme Court, those decisions run counter to the decisions of the Supreme Court and other courts of appeals. However, for purposes of the present motion, the Federal Circuit’s affirmance of the IPR FWD has immediate preclusive effect and warrants granting Liquidia’s requested relief.

has stated in this very matter that: “Consistent with the Federal Circuit’s guidance, district courts do not apply collateral estoppel effect to the PTAB’s ruling *until the ruling is affirmed*[.]” D.I. 428 at 2 (emphasis added). As UTC recognized, because the PTAB’s FWD invalidating all claims of the ’793 patent has been affirmed, the ’793 patent is invalid and can no longer be enforced. UTC’s attempt to now argue otherwise should not be countenanced.

UTC’s own actions prove that the ’793 patent is no longer legally enforceable. As this Court is aware, UTC filed on November 20, 2023, an Amended Complaint again asserting the ’793 patent against Liquidia. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 1:23-cv-00975-RGA, D.I. 8 (D. Del. Nov. 30, 2023). Liquidia filed a motion to dismiss Counts I and II of the amended complaint directed to UTC’s allegations of infringement of the ’793 patent. *Id.*, D.I. 13. Recognizing that it can no longer legally assert the ’793 patent against Liquidia because of the preclusive nature of the Federal Circuit’s affirmance of the PTAB’s ’793 FWD, UTC has voluntarily dismissed its ’793 infringement claims. *Id.* at D.I. 17. UTC dismissed its ’793 complaint despite the fact that its request for rehearing *en banc* is pending (filed on January 19, 2024), the Federal Circuit has not issued its mandate, the PTO Director has not yet cancelled the ’793 patent claims, and the ’793 patent has not been de-listed from the Orange Book.<sup>2</sup> And by dismissing its infringement claims concerning the ’793 patent, this would immediately remove any barrier from the FDA granting final NDA approval for Yutrepia<sup>TM</sup>—that is, any barrier but for the

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<sup>2</sup> UTC contends that because the ’793 patent is still listed in the Orange Book for Tyvaso®, an ANDA applicant would still have to provide a Paragraph IV certification to UTC. D.I. 465 at 14. While technically true, because of the Federal Circuit’s affirmance of the PTAB’s FWD invalidating the ’793 patent, collateral estoppel prevents UTC from asserting that patent against the ANDA applicant, thereby allowing the FDA to grant final FDA approval of the ANDA. Liquidia should be in the same position.



Court’s current injunction in this action. These are the very type of extraordinary circumstances that warrant relief from judgment under Rule 60(b).

### **C. Liquidia Has Satisfied the Requirements of Rule 60(b)**

Because the Federal Circuit’s affirmance has an immediate effect nullifying the legal basis for this Court’s Final Judgment, Liquidia has satisfied the requirements of Rule 60(b). UTC attempts to make much of the fact that the Court’s injunction was statutorily based. *See* D.I. 465 at 5, 10. But Rule 60(b) makes no such distinction, and UTC cites no case establishing Rule 60(b) is inapplicable to statutorily based injunctions.<sup>3</sup>

As UTC points out, in the context of Rule 60(b)(5), the Third Circuit instructs courts to consider a number of factors in assessing relief, including “the circumstances leading to entry of the injunction and the nature of the conduct sought to be prevented; the length of time since entry of the injunction; whether the party subject to its terms has complied or attempted to comply in good faith with the injunction; and the likelihood that the conduct or conditions sought to be prevented will recur absent the injunction” as well as “whether the conduct previously enjoined has become legal due to a change in the law.” D.I. 465 at 5, 10 (quoting *Bldg. & Const. Trades Council of Phil. & Vicinity, AFL-CIO v. N.L.R.B.*, 64 F.3d 880, 888 (3d Cir. 1995)). Liquidia satisfies these requirements.

Contrary to UTC’s contention (D.I. 465 at 10), the circumstances leading to the entry of the infringement and injunction ruling have changed because the ’793 patent is no longer valid—claim cancellation by the PTO is not needed for invalidity. *See Worden v. Searls*, 121 U.S. 14, 24-

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<sup>3</sup> UTC’s emphasis of the statutory basis for the injunction as rationale to maintain the injunction is particularly inapt here given the express language in that very statutory regime: the approval of the enjoined product should occur on “the date on which the court of appeals decides that the patent is invalid.” *See* 21 U.S.C. Section 355(c)(3)(C)(ii)(I).

27 (1887) (finding a reissue patent invalid and a preliminary injunction was unwarranted as a matter of law as the “right to the injunction . . . was founded on the validity of [the] patent.”); *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 644 (2015) (“To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed.”). The injunction has already been in place for over a year, giving UTC extended exclusivity based on an invalid patent. Furthermore, Liquidia and the FDA have unquestionably complied with the injunction. Finally, the conduct sought to be prevented—blocking final FDA approval of Yutrepia<sup>TM</sup>—cannot recur because, as discussed above, UTC has already dismissed another patent infringement lawsuit brought against Liquidia involving the ’793 patent, which can lead to direct and unencumbered final FDA approval. These circumstances lend support to granting Liquidia’s Rule 60 Motion.

UTC’s reliance on *WesternGeco L.L.C. v. ION Geophysical Corp.*, 913 F.3d 1067, (Fed. Cir. 2019), for the proposition that this Court cannot reopen the case to grant Liquidia’s requested relief until the ’793 patent claims are cancelled is misplaced. D.I. 465 at 12. In *WesternGeco*, the issue was whether the parties’ agreement regarding the payment of a reasonable royalty could be reversed because of invalidation of the patents at issue. 913 F.3d at 1071–72. As the Federal Circuit noted, *the parties stipulated to the payment of a reasonable royalty*, which was reflected in a joint motion filed in *June 2017*, despite the fact that the PTAB IPR decision invalidating the patents had issued in *December 2015*. *Id.* Based on “these unique circumstances,” the Federal Circuit did not disturb that agreement. *Id.* Here, there has been no agreement between the parties, and the PTAB’s ’793 patent FWD issued *before* this Court rendered its decision and entered judgment. Now that the IPR FWD has been affirmed, the “unique circumstances” in this case warrant relief from judgment under Rule 60(b)(5) and (6).

UTC further contends that relief under Rule 60(b)(6) is not warranted based on Liquidia's decision to bring an IPR proceeding. D.I. 465 at 1, 6, 11. But UTC cites no authority to support its position that Liquidia's decision to bring an IPR proceeding somehow limits the preclusive effect of the decision in that IPR proceeding.<sup>4</sup> Even if there was such authority, UTC misconstrues the facts. Liquidia's decision to file an IPR petition was based on UTC's strategic choice to file a motion to dismiss Liquidia's invalidity counterclaim and defense with respect to the '793 patent on the basis of assignor estoppel. D.I. 29. The Court denied UTC's Motion (D.I. 45), but UTC continued to assert assignor estoppel throughout the pre-trial process. D.I. 322, Ex. 4 (Plaintiff's Statement of Contested Issues of Law) at ¶¶ 136-140. Because assignor estoppel does not apply to IPR proceedings, Liquidia filed its ultimately successful petition. Moreover, that Liquidia did not present obviousness to the district court was again based on UTC's strategic decision to file a pre-trial motion in limine seeking to apply IPR estoppel *before* the '793 IPR had been decided. D.I. 439 at 2–4. Importantly, Liquidia never abandoned its arguments before this Court and the PTAB that the '793 patent was invalid. This is in stark contrast to the parties in *Coltec Industries, Inc. v. Hobgood*, 280 F.3d 262, 267 (3d Cir. 2002), cited by UTC, who voluntarily dismissed their claims of unconstitutionality of the Coal Act, but then subsequently sought relief under Rule 60(b) based on a later decision rendering the Coal Act unconstitutional. *Id.* at 271–724. The Third Circuit affirmed the denial of Coltec's Rule 60(b)(6) motion because Coltec was attempting to “escape the effects of a bargain it regretted in hindsight[.]” thereby failing to meet the exceptional

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<sup>4</sup> In fact, Congress intended IPRs to take place concurrently with district court proceedings. *See, e.g.* 35 U.S.C. §§ 315(b) (requiring IPR to be sought within one year of service of a patent infringement complaint); § 315(e)(2) (precluding a challenger from asserting invalidity grounds in district court that they could have raised in the IPR). Liquidia's choice to file an IPR aligns with congressional intent. Any decision penalizing Liquidia's choice of procedure discourages future litigants from pursuing an IPR before the PTAB, which in turn increases the burden on district courts and costs on the parties.

Finally, as presented in Liquidia's opening brief, relief from judgment is especially warranted here given the inequities that maintaining the Final Judgment would cause. D.I. 462 at 7–8. The facts here prove Liquidia does stand “differently” from other potential defendants. D.I. 465 at 14. As discussed above, based on Liquidia's motion to dismiss, UTC voluntarily dismissed its '793 patent infringement allegations against Liquidia in a second lawsuit. *See* §I.B., *supra*. And UTC would not be able to assert the '793 patent against any other 505(b)(2) NDA applicant or generic ANDA applicant because of the collateral estoppel effect of the now affirmed PTAB's '793 FWD, thus removing the '793 patent as a basis to prevent final FDA approval for any other applicant. UTC, however, is attempting to continue to enjoin Liquidia based solely on the '793 patent when it legally cannot do the same against others. UTC cannot on the one hand dismiss a legally improvident lawsuit based on the '793 patent and, on the other hand, continue to assert that this Court must continue to enforce an injunction against Liquidia based on that same patent. Any decision denying the relief requested leads to an absurd result allowing third parties to escape liability on the '793 patent based on the work done by Liquidia, only to have Liquidia wait longer

for entry into the market. Accordingly, Liquidia respectfully requests its motion under Rule 60(b)(5) and (6) be granted.

## II. CLAIM CANCELLATION UNDER 35 U.S.C. § 318 IS NOT REQUIRED

UTC maintains that the Federal Circuit’s affirmance of invalidity has no effect, and thus relief under Rule 60(b) cannot be granted until the claims are canceled by the PTO under 35 U.S.C. § 318, which occurs after UTC has an opportunity to petition for rehearing, the Federal Circuit issues its mandate, and all appeals are exhausted.<sup>5</sup> That these actions are outstanding does not negate the immediate preclusive effect the ’793 Patent Federal Circuit Decision has on this action and does not warrant denial of Liquidia’s requested relief. In *XY*, the Federal Circuit dismissed a co-pending appeal on the same day it issued its affirmance of the PTAB’s decision on that same patent—it did not wait for any decision on rehearing, mandate, or claim cancellation. *XY*, 890 F.3d at 1294. Similarly, UTC dismissed its ’793 patent infringement allegations against Liquidia in a recently filed suit, and did not wait for a decision on rehearing, did not wait for the Federal Circuit’s mandate, and did not wait for claim cancellation under § 318. *See* § I.B. If UTC believed all of these procedural requirements must be met before the Federal Circuit’s affirmance has any legal effect, then it certainly would not have voluntarily dismissed its recently filed ’793 patent action. The same rationale applies here—the potential pendency of other procedural actions does not diminish either the finality or the binding effect of the ’793 Patent Federal Circuit Decision.

Additionally, it is not claim cancellation that makes a patent invalid, but a judgment of invalidity—a judgment currently before this Court. Courts have consistently held that

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<sup>5</sup> UTC filed its request for rehearing *en banc* of the Federal Circuit’s decision affirming the PTAB’s ’793 patent FWD on January 19, 2024. UTC contends Liquidia cited no statistics related to the likelihood that UTC’s rehearing request of a non-precedential decision will be denied. D.I. 465 at 8. UTC misunderstands Liquidia’s argument, though, which is based on what the Federal Circuit has already done, not what it will do in the future. Also, it is noteworthy that UTC cites no case where panel or *en banc* rehearing of a non-precedential decision was granted.

<sup>6</sup> The Court has also stated that “[i]f the Federal Circuit upholds the invalidity of the asserted ’793 claims as obvious, it appears that Liquidia could launch its product.” D.I. 460 at 2.

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For these reasons and those presented in Liquidia’s opening brief, Liquidia respectfully requests that the Court grant post judgment relief.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 20-755 (RGA)  
 )  
LIQUIDIA TECHNOLOGIES, INC., )  
 )  
Defendant. )

**PLAINTIFF'S LETTER BRIEF IN SUPPORT OF MOTION TO STAY**

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April 1, 2024

Dear Judge Andrews:

United Therapeutics Corporation (“UTC”) respectfully moves this Court to stay its Order (D.I. 479) and Amended Final Judgment (D.I. 480) (collectively, “Rule 60(b) Decision”) granting Liquidia Technologies, Inc.’s (“Liquidia”) Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b) pending UTC’s forthcoming appeal to the Federal Circuit.

This Court’s Rule 60(b) Decision “vacate[d] the portion of the final judgment that blocks the final approval of Liquidia’s NDA.” D.I. 479. A stay of that decision pending appeal is necessary because now, no court order enjoins Liquidia’s imminent launch of its proposed Yutrepia™ product and a launch of Yutrepia would irreparably harm UTC while its request for review by the Supreme Court is forthcoming. By contrast, a stay will preserve the status quo and allow the Federal Circuit to address the issue of first impression that UTC’s appeal raises regarding when an agency decision becomes binding on a district court final judgment in a closed case, *before* the market is prematurely flooded with Liquidia’s follow-on product. As shown below, such relief is warranted under the circumstances.

## **I. This Court Should Stay Its Order and Amended Final Judgment Pending Appeal**

Courts consider four factors in deciding whether to grant a stay pending appeal: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunsell*, 481 U.S. 770, 776 (1987); *In re Revel AC, Inc.*, 802 F.3d 558, 565 (3d Cir. 2015) (applying the same standard). “There is substantial overlap between these and the factors governing preliminary injunctions . . . because similar concerns arise whenever a court order may allow or disallow anticipated action before the legality of that action has been conclusively determined.” *Nken v. Holder*, 556 U.S. 418, 434 (2009).

In considering whether to grant a stay pending appeal, this Court uses a “sliding scale approach” in which “the four factors [are] effectively [] merged” and the court “assesses [the] movant’s chances for success on appeal and weighs the equities as they affect the parties and the public.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537 (D. Del. 2005) (quoting *Standard Havens*, 897 F.2d at 513). Thus, “[w]hen harm to applicant is great enough, a court will not require ‘a strong showing’ that applicant is ‘likely to succeed on the merits.’” *Standard Havens*, 897 F.2d at 513 (quoting *Hilton*, 481 U.S. at 776). Rather, “if the harm factors weigh heavily in movant’s favor, it need only demonstrate a substantial case on the merits.” *Jacobson v. Lee*, 1 F.3d 1251 (Fed. Cir. 1993).

### **A. UTC Can Win on the Merits or, at Least, Present a Substantial Case, and Will Suffer Significant Irreparable Harm Absent a Stay**

UTC’s appeal is likely to succeed on the merits or, at least, present a substantial case, because the Court’s reliance on *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282 (Fed. Cir. 2018) was misplaced. As a preliminary matter, UTC does not take issue with Your Honor’s recognition that under Federal Circuit precedent, a court of appeals’ “affirmance renders final a judgment on the invalidity of the [asserted claims], and has an *immediate* preclusive effect on any pending or co-pending actions involving the patent.” D.I. 479 (quoting *XY, LLC*, 890 F.3d at 1294) (alteration in original). However, the reach of *XY* explicitly extends only so far as to *pending or co-pending*

Hon. Richard G. Andrews  
Page 2

April 1, 2024

actions. Relevant here, *XY* does not address whether an affirmance of a lower tribunal’s judgment of invalidity has a preclusive effect on *terminated* cases involving the same patent. Indeed, when an agency decision becomes binding on a district court final judgment in a *closed* case presents an issue of first impression for the Federal Circuit, on which UTC is likely to prevail.

Put plainly, this case was terminated and closed once Liquidia’s petition for a writ of certiorari was denied. The ’793 IPR is not yet terminated or closed until the Supreme Court decides UTC’s forthcoming petition for a writ of certiorari, and if granted, until the Supreme Court’s merits review is complete. The ’793 IPR determination should not upend the terminated and closed case, let alone before UTC has fully exhausted its appellate rights with respect to the ’793 IPR.

UTC would suffer irreversible and irreparable harm if the Supreme Court grants review after this Court unwinds the portion of the Final Judgment (D.I. 436) that blocks the final approval of Liquidia’s NDA. In particular, even if Yutrepia were ultimately withdrawn from the market after launch, the injury to UTC would nevertheless be irreparable “because market share is so difficult to recover.” *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2016 WL 5348866, at \*13 (D.N.J. Sept. 23, 2016). Liquidia’s premature access to the market for dry powder formulations of treprostinil would also erode UTC’s first-mover advantage and facilitate Liquidia’s ability to re-launch when the ’793 patent expires, imposing a severe harm on UTC that would be difficult to quantify. *Cf. United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 23-975, D.I. 29 ¶ 91.

Moreover, the severity of irreparable harm to UTC absent a stay tips the scales in favor of granting a stay. *Standard Havens*, 897 F.2d at 513. With this Court’s decision to grant Liquidia’s 60(b) motion, no court order enjoins Liquidia from launching Yutrepia, and indeed, Liquidia has announced that it will launch Yutrepia immediately upon FDA approval. Ex. A (Feb. 26, 2024 Email Thread); Ex. B (Liquidia Press Release, Mar. 13, 2024). If Liquidia is allowed to prematurely launch its competing product, UTC will be irreparably harmed in several ways, including lost market share, price erosion, and reputational harm, that are irreversible, impossible to quantify with precision, and that Liquidia cannot rectify. For example, a Yutrepia launch would result in demands from payors for additional rebates or discounts, causing lasting price erosion to UTC’s Tyvaso products even if Yutrepia were removed from the market. *See* No. 23-cv-975, D.I. 29 ¶¶ 16, 18, 63–76; D.I. 26 at 16–17. Additionally, Yutrepia would directly compete with UTC’s Tyvaso products, eroding UTC’s sales and market share and making it “impossible to restore [UTC]’s . . . exclusive position by an award of damages and a permanent injunction.” *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996); No. 23-975, D.I. 29 ¶¶ 17, 86–95, D.I. 26 at 17–18. Even if some of the harm to UTC from Liquidia’s Yutrepia launch is quantifiable, the harm to UTC is irreparable because Liquidia is likely unable to compensate UTC— notwithstanding Liquidia’s most recent funding efforts. A stay of the Rule 60(b) Decision pending appeal is the only remedy to protect UTC from this harm.

Unless and until the claims of the ’793 patent are canceled following exhaustion of all of UTC’s appellate rights, Liquidia should not have been excused from this Court’s judgment. The Federal Circuit has already explained in this very case that “the Board’s final written decision does not cancel claims; the claims are canceled when the Director issues a certificate confirming unpatentability, which occurs only after ‘the time for appeal has expired or any appeal has terminated.’” *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1372 (Fed. Cir. 2023) (quoting 35 U.S.C. § 318). Here, while the Federal Circuit’s mandate in the IPR appeal has issued, the USPTO has not issued a certificate cancelling the claims of the ’793 patent. Only then

Hon. Richard G. Andrews  
Page 3

April 1, 2024

does a patent “no longer confer[] any rights that support an injunction.” *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1356 (Fed. Cir. 2015).

At a minimum, the Court should grant a temporary stay to allow time for the Federal Circuit to consider whether to enter a stay of the Rule 60(b) Decision pending merits review of this issue.

### **B. The Balance of Equities Favors Granting a Stay**

Liquidia will suffer minimal, if any, harm as a result of a stay pending appeal. Liquidia’s position will not change if the stay is granted, as it has not launched yet and a stay would merely maintain the status quo. Any harm to Liquidia would last only for the time it takes to resolve UTC’s appeal. In other words, Liquidia will be in the *same exact position* as it is today if a stay pending appeal is granted. *Impax Lab’ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (finding minimal hardship where defendant will be “in the same position as it was in before the injunction was granted”). Further, a stay would not threaten Liquidia’s ability to continue operating; Liquidia has recently touted to the public that it is “very well capitalized” and that, in light of “the \$126 million that [it] has raised,” it has “never been in a stronger position.” No. 23-975, D.I. 27 Ex. 3 at 7–8, 12–13 (“[W]e have the proper amount of fuel to really fire it on all cylinders on all things we’re trying to achieve.”).

In any event, any harm to Liquidia for having to wait to launch on the PAH indication is self-inflicted, and therefore *de minimis*. Liquidia cannot raise a cognizable harm that it will suffer as a result of the stay because any delay-related harm that Liquidia will suffer is a result of its own decision to litigate the alleged obviousness of the ’793 patent in an IPR instead of before this Court. *Pappan Enters., Inc. v. Hardees Food Sys., Inc.*, 143 F.3d 800, 806 (3d Cir. 1998) (tipping scale in favor of proponent because any harm to the party opposing relief was “self-inflicted”).

Moreover, the public interest favors resolving UTC’s appeal of the Rule 60(b) Decision before the market is prematurely flooded with Liquidia’s follow-on product. Courts have recognized that “[t]he fundamental purpose of a stay pending appeal is the preservation of the status quo.” *See, e.g., In re Zohar III, Corp.*, 2019 WL 6910285, at \*8 (D. Del. Dec. 19, 2019). Likewise, granting UTC’s request for a stay of the Rule 60(b) Decision pending appeal serves the public interest by fulfilling the precise “fundamental purpose” for which the stay mechanism was intended. *See id.*; *see also, e.g., Howard Johnson Int’l, Inc. v. Univ. Hosp., LLC*, 2018 WL 2095595, at \*3 (D.N.J. May 7, 2018) (“Defendant is correct that there is an interest in maintaining the status quo while an appeal is pending”). Recognizing this fundamental purpose, this Court has imposed temporary stays pending appeal to allow appellate review of adverse Patent Office actions in the past. *E.g., Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 2008 WL 5351038, at \*1 (D. Del. Dec. 22, 2008). As explained above, if Your Honor does not grant the requested stay, the impending launch of Liquidia’s Yutrepia product will irreversibly destroy the status quo, depleting UTC’s assets while it is simultaneously left to expend additional resources to prosecute the instant issue of first impression in the Federal Circuit. Once Liquidia’s figurative barn-door has been opened, it can never be reclosed.

## **II. Conclusion**

For these reasons, UTC respectfully requests that this Court stay the Rule 60(b) Decision pending UTC’s appeal to the Federal Circuit. In the alternative, at a minimum, the Court should stay the Rule 60(b) Decision for 14 days to allow UTC to petition the Federal Circuit for a permanent stay pending appeal.





# EXHIBIT A

**From:** Sukduang, Sanya <ssukduang@cooley.com>  
**Sent:** Monday, February 26, 2024 6:05 PM  
**To:** Jackson, William C; Flynn, Michael J.  
**Cc:** Davies, Jonathan; kkeller@shawkeller.com; Nate Hoeschen; Dcarsten@mwe.com; Cheng, Katherine; Adykhuis@mwe.com; aburrowbridge@mwe.com; Lobel, Louis; Romeo, Eric; Mhkim@mwe.com; z/Liquidia v UTC 308970-201  
**Subject:** [EXT] RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

William,

We agree a TRO is a waste of time, resources and not well supported. This is an issue completely of UTC's own making. UTC knew from the date of FDA approval of PH-ILD that its regulatory exclusivity would expire at the end of March 2024. UTC filed suit in September 2023 asserting the 793 patent based on Liquidia's addition of PH-ILD and knew Liquidia intended to launch upon FDA approval. Yet, UTC did not file a PI at that time. UTC amended its complaint on November 30, 2023 to add the '327 patent, knowing Liquidia would launch and knowing the date of expiry of regulatory exclusivity—no PI was filed. On December 6, 2023, upon a direct request from you, Liquidia expressly and unequivocally informed UTC that it will launch upon final FDA approval. UTC did not file a PI then. Thus, the immediacy and harm UTC alleges is a fallacy and nonetheless, caused by UTC. These facts are not in dispute.

Liquidia will not agree to delay launching until resolution of UTC's PI motion.

Thanks  
 Sanya

**From:** Jackson, William C <WJackson@goodwinlaw.com>  
**Sent:** Monday, February 26, 2024 5:02 PM  
**To:** Sukduang, Sanya <ssukduang@cooley.com>; Flynn, Michael J. <mflynn@morrisnichols.com>  
**Cc:** Davies, Jonathan <jdavies@cooley.com>; kkeller@shawkeller.com; Nate Hoeschen <nhoeschen@shawkeller.com>; Dcarsten@mwe.com; Cheng, Katherine <KatherineCheng@goodwinlaw.com>; Adykhuis@mwe.com; aburrowbridge@mwe.com; Lobel, Louis <LLobel@goodwinlaw.com>; Romeo, Eric <ERomeo@goodwinlaw.com>; Mhkim@mwe.com; z/Liquidia v UTC 308970-201 <zLiquidiaUTC308970201@cooley.com>  
**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

[External]

Sanya:

It has occurred to us that the briefing schedule that you requested means that UTC's regulatory exclusivity on ILD will expire before the briefing on the PI is complete. It is possible that the FDA may act in the interim. Will Liquidia agree not to launch before Judge Andrews rules on the preliminary injunction motion? If not, we will be forced to file a request for a temporary restraining order, which we think is a waste of time and resources.

Let us know.

William C Jackson



Goodwin Procter LLP



\*\*\*EXTERNAL\*\*\*

**[External]**

1. **Question 1:** Liquidia currently is enjoined from launching based on the judgment from the prior D. Del. case. But Liquidia has a pending Rule 60 motion for relief from that judgment. The Court could rule on that motion at any time. Should that motion be granted, there would be no impediment to Liquidia launching its LIQ861 product. Should the Court grant the motion and Liquidia launch its product for ILD, UTC would be irreparably harmed. **UTC proposed that, in order to avoid having to brief a preliminary injunction now, the parties agree that, if the Court were to grant the pending Rule 60 motion in the prior case, UTC would have 5 days to file a preliminary injunction motion and Liquidia would not launch its product for the ILD indication**

during the pendency of those preliminary injunction proceedings. Such an agreement would obviate the need for a preliminary injunction motion now (and potentially at all). Liquidia has now rejected that proposal.

2. **Question 2:** The APA action against the FDA asserts that the FDA violated its own “Bundling Rule” and allowed Liquidia to seek to add the ILD indication as an amendment rather than a separate NDA. Those proceedings, alleging a violation of the Administrative Procedures Act, are entirely distinct from these proceedings in which UTC alleges that Liquidia is infringing its ’327 patent. Nor is Liquidia even a party to those proceedings.
3. **Questions 3-4:** The parties did meet and confer in December about entirely different issues in this case. During that conversation, the possibility of a preliminary injunction was referenced. But I believe the focus of the meet and confer in December was the schedule for Liquidia answering or otherwise responding to the Amended Complaint that UTC had filed.
4. **Question 5:** As I indicated, in the NC case UTC has consistently sought to accommodate both parties’ reasonable scheduling requests. By contrast, after providing an expert report in the NC case, Liquidia stated that its expert was available for deposition on a single day in the entire expert discovery period, including weekends, and refused to agree to extend the expert discovery period to accommodate the schedules of those involved. It was for that reason that we were forced to seek the NC court’s assistance. We are corresponding with you and NC counsel with respect to the proposal to adjust the NC expert deposition calendar.
5. **Questions 6-8:** We agree with your summaries below and look forward to hearing from you with respect to the deposition dates for Dr. Nathan and Mr. Selck.

We are available should Liquidia believe that further meet and confer efforts would be productive. Thanks.

William C Jackson



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---

**From:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Sent:** Friday, February 23, 2024 4:47 PM  
**To:** Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
**Cc:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>; [Dcarsten@mwe.com](mailto:Dcarsten@mwe.com); Cheng, Katherine <[KatherineCheng@goodwinlaw.com](mailto:KatherineCheng@goodwinlaw.com)>; [Adykhuism@mwe.com](mailto:Adykhuism@mwe.com); [aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com); Lobel, Louis <[LLobel@goodwinlaw.com](mailto:LLobel@goodwinlaw.com)>; Romeo, Eric <[ERomeo@goodwinlaw.com](mailto:ERomeo@goodwinlaw.com)>; [Mhkim@mwe.com](mailto:Mhkim@mwe.com); z/Liquidia v UTC 308970-201 <[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>  
**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

\*\*\*EXTERNAL\*\*\*

Counsel,

I write to summarize the parties’ meet and confer concerning UTC’s anticipated PI motion, which was attended by Sanya Sukduang, Karen Keller, and Lauren Strosnick for Liquidia and William Jackson, Doug Carsten, and Michael Flynn for UTC.

The parties addressed the questions presented below.

Question 2, UTC asserted that the APA action against the FDA seeks different relief than the proposed PI. Liquidia disagreed, indicating that the PI seeks to enjoin Liquidia from launching in PH-ILD and UTC's FDA action seeks to compel the FDA to revoke any approval of Yutrepia for PH-ILD and force Liquidia to refile. In short, both seek to enjoin Liquidia from launching Yutrepia in PH-ILD.

Questions 3-4, UTC asserted that it became aware of “recent” press release regarding Liquidia’s anticipated launch and this “recent” notice was required to file a PI. UTC acknowledged, however, that the parties did conduct a meet and confer prior to December 25, 2023 (the exact date was December 6, 2023), where Liquidia provided notice, as expressly requested by UTC’s counsel Mr. Jackson, that it would launch Yutrepia immediately upon FDA approval. UTC’s counsel also agreed that during the December 6, 2023 meet and confer, Mr. Flynn suggested the parties contact the Court to address a PI briefing schedule.

Question 5, Liquidia asked if UTC would be amenable to postpone the UTC witness expert depositions in the NC trade secret case, to which UTC said it was. **Liquidia will submit a proposal to NC counsel shortly.**

Question 6, UTC indicated it intends to file its PI motion on Monday or Tuesday of next week.

Question 7, UTC has identified 2 experts (Dr. Nelson and Mr. Selck). Dr. Nelson is available for deposition on March 10 and Mr. Selck sometime thereafter. Liquidia is looking to see if those dates work.

Question 8, Liquidia requests an extension, until **April 5, 2024** to file its opposition, which UTC indicated it would consent to. UTC's requested two-weeks after Liquidia files its opposition to file its reply, to which Liquidia consents.

Thanks  
Sanya

**From:** Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
**Sent:** Thursday, February 22, 2024 12:50 PM  
**To:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Cc:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; William Jackson (Goodwin) <[wjackson@goodwinlaw.com](mailto:wjackson@goodwinlaw.com)>; Douglas H. Carsten - McDermott Will & Emery LLP ([dcarsten@mwe.com](mailto:dcarsten@mwe.com)) <[dcarsten@mwe.com](mailto:dcarsten@mwe.com)>; Cheng, Katherine <[KatherineCheng@goodwinlaw.com](mailto:KatherineCheng@goodwinlaw.com)>; Art Dykhuis - McDermott Will & Emery LLP ([adykhuis@mwe.com](mailto:adykhuis@mwe.com)) <[adykhuis@mwe.com](mailto:adykhuis@mwe.com)>; Burrowbridge, Adam W. (MWE) <[aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com)>; Lobel, Louis <[LLobel@goodwinlaw.com](mailto:LLobel@goodwinlaw.com)>; Romeo, Eric <[ERomeo@goodwinlaw.com](mailto:ERomeo@goodwinlaw.com)>; [Mhkim@mwe.com](mailto:Mhkim@mwe.com); z/Liquidia v UTC 308970-201 <[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>  
**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

**[External]**

Sanya,

We are available at 12:00 ET on Friday for a call and look forward to discussing your questions below.

Click to join meeting: <https://meet.loopup.com/45xeX0IXC8>

**Or dial in:**





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# EXHIBIT B





litigation in the U.S. District Court for the District of Delaware, inter partes review proceedings conducted at the PTAB or other litigation instituted by United Therapeutics or others, including rehearings or appeals of decisions in any such proceedings, the issuance of patents by the USPTO and our ability to execute on our strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable decisions of courts or other tribunals are not determinative of the outcome of the appeals or rehearings of the decisions. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the SEC, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

## Company Contacts

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Chief Business Officer  
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[jason.adair@liquidia.com](mailto:jason.adair@liquidia.com)

### Media Inquiries:

[media@liquidia.com](mailto:media@liquidia.com)

## Liquidia Corporation Select Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 83,679	\$ 93,283
Total assets	\$ 118,332	\$ 129,198
Total liabilities	\$ 71,039	\$ 38,776
Accumulated deficit	\$ (429,098)	\$ (350,596)
Total stockholders' equity	\$ 47,293	\$ 90,422

## Liquidia Corporation Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue	\$ 17,488	\$ 15,935
Costs and expenses:		
Cost of revenue	2,888	2,859
Research and development	43,242	19,435
General and administrative	44,742	32,411
Total costs and expenses	90,872	54,705
Loss from operations	(73,384)	(38,770)
Other income (expense):		
Interest income	3,466	1,090
Interest expense	(6,273)	(2,338)
Loss on extinguishment of debt	(2,311)	(997)
Total other income (expense), net	(5,118)	(2,245)
Net loss and comprehensive loss	\$ (78,502)	\$ (41,015)
Net loss per common share, basic and diluted	\$ (1.21)	\$ (0.67)
Weighted average common shares outstanding, basic and diluted	64,993,476	60,958,862





IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 20-755-RGA  
 )  
LIQUIDIA TECHNOLOGIES, INC., )  
 )  
Defendant. )

**DEFENDANT'S LETTER BRIEF IN OPPOSITION OF MOTION TO STAY**

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*Attorneys for Defendant Liquidia  
Technologies, Inc.*

Dated: April 4, 2024

Dear Judge Andrews:

Liquidia Technologies Inc. (“Liquidia”) respectfully asks this Court to deny United Therapeutics Corporation’s (“UTC”) request for a stay of enforcement (D.I. 485) of this Court’s Order (D.I. 479) and Amended Final Judgment (D.I. 480) (collectively the “Rule 60(b) Decision”). A stay of the Rule 60(b) Decision is unwarranted and would only prolong the harm Liquidia and the public have already incurred since the PTAB’s July 19, 2022 finding of invalidity.

The *Hilton* factors, which are used to analyze whether to stay a judgment, all mandate denial of a stay.<sup>1</sup> “The party requesting a stay bears the burden of showing that the circumstances justify an exercise of that discretion” which UTC has not done here. *Nken v. Holder*, 556 U.S. 418, 433–34 (2009). UTC contends, without a single case in support, that this Court’s Rule 60(b) Decision will be reversed on appeal. It further overstates the harm it might suffer while ignoring contrary public statements by its own CEO, and minimizes the adverse impact on Liquidia and the public.

### **I. UTC Will Not Succeed on the Merits**

As this Court recognized, likelihood of success on the merits is the most important *Hilton* factor. (D.I. 460, 2.) Despite submitting its brief opposing Liquidia’s post-judgment relief *and* three separate letters related to Notices of Supplemental Authority (*see* D.I. 465, D.I. 470, D.I. 475, D.I. 478), UTC argues for the first time that the Court’s Rule 60(b) Decision comes too late as this case is “closed,”—an issue UTC claims is one of first impression. (D.I. 485, 2.) Even more bold, UTC asserts it will prevail despite citing no case law to support the notion that this Court’s order was in error or untimely. There is no basis for UTC to assert it is likely to succeed on the merits. And to the extent UTC relies on a yet-to-be filed certiorari petition to the Supreme Court challenging the Federal Circuit’s affirmance of the PTAB’s ’793 FWD as a basis for success, UTC ignores the fact that the PTAB found the ’793 patent invalid, that decision was confirmed by the PTAB in a rehearing denial, affirmed by the Federal Circuit in a non-precedential decision, and rehearing was denied without comment.<sup>2</sup>

With respect to the Court’s reliance on *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282 (Fed. Cir. 2018) in granting Liquidia’s Rule 60(b) motion, *XY* states that the affirmance of a final judgment on invalidity “has an immediate issue-preclusive effect on any pending or co-pending actions[.]” *Id.* at 1294. That “immedia[cy]” took effect on the date of the Federal Circuit’s decision—December 20, 2023—and UTC does not dispute that this case was still pending as of

---

<sup>1</sup> These factors include: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).

<sup>2</sup> Just as the Court indicated it had no basis to evaluate the likelihood of success of Liquidia’s appeal of the PTAB’s ruling on the ’793 patent—a different proceeding—there is no basis here to evaluate the likelihood of success of UTC’s future certiorari petition regarding the same PTAB ruling, now affirmed on appeal. (D.I. 460, 3.)



that date.<sup>3</sup> That the Court issued its decision afterwards does not change the result. Additionally, UTC cites nothing in Rule 60 itself or any cases addressing Rule 60 preventing the Court from modifying its judgment even after the decision becomes final. Indeed, the Court has the discretion under Rule 60 to relieve a party from a final judgment if: “(5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or (6) any other reason that justifies belief.” Fed. R. Civ. P. 60(b); (*see also* D.I. 479, 2).

Finally, UTC continues to overlook the fundamental principle that an invalid patent cannot give rise to an injunction. *See Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573, 1578 (Fed. Cir. 1994) (recognizing that upholding an injunction based on a patent would be at odds with the Court’s historical treatment of patents it recently declared invalid); *Blonder-Tongue Lab’ys, Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 350 (1971) (holding that issue preclusion (collateral estoppel) applies where a party “fac[es] a charge of infringement of a patent that has once been declared invalid”). This principle is especially sound here since the Hatch-Waxman Act, which formed the basis of the Court’s original injunction, expressly directs that final FDA approval of a § 505(b)(2) NDA is granted on “the date on which the court of appeals decides that the patent is invalid[.]” *See* 21 U.S.C. § 355(c)(3)(C)(ii)(I).<sup>4</sup> In light of this, UTC has not demonstrated it is likely to succeed on the merits of its appeal warranting a stay of judgment.

## II. By Its Own Admission, UTC Will Not Suffer Irreparable Harm

UTC contends that it would suffer irreversible and irreparable harm if a stay is not granted. (D.I. 485, 2.) But UTC grossly exaggerates the harm that it would allegedly suffer. In its brief, UTC claims that a Yutrepia<sup>TM</sup> launch would “directly compete with UTC’s Tyvaso products, eroding UTC’s sales and market share[.]” (*Id.*) On the contrary, in 2023, UTC’s CEO, Dr. Rothblatt, explained that “Liquidia, if approved, also **does not challenge our projected double-digit growth**[.]” because Yutrepia<sup>TM</sup> is “**not a generic product**, but is instead a strongly differentiated drug device product[.]”<sup>5</sup> (Ex. 1 (Q1 2023 UTC Earnings Call), at 3 (emphasis added).) Dr. Rothblatt also stated that “there is so much robust room for growth and improvement in pulmonary hypertension[.]” and that UTC “welcome[s] any new agent that can help the health of the pulmonary hypertension patient population.” (Ex. 2 (Q4 2022 UTC Earnings Call), at 10.) And to this point, Dr. Rothblatt explained that “the experience has been that when new agents have been introduced into the market, **it has grown the market** for all of the existing patients.” (*Id.* (emphasis added).) This presumably includes Yutrepia<sup>TM</sup>. In **March 2024**, UTC’s President and

<sup>3</sup> UTC further argues that the ’793 patent is not invalidated until the claims are canceled by the PTO Director, repeating an argument the Court has already rejected. (*See* D.I. 485, 2–3; D.I. 479, 5.) And UTC does not dispute there that claim cancellation is “a nondiscretionary formality[.]” *See Sec. People, Inc. v. Iancu*, 971 F.3d 1355, 1361 (Fed. Cir. 2020); (*see also* D.I. 479, 5). Nonetheless, the cancellation of the ’793 patent claims will occur shortly, rendering moot any argument UTC has here, or before the Federal Circuit.

<sup>4</sup> Notably, in the past UTC has taken the position that the statutory nature of Hatch-Waxman cases cannot be stayed, which directly contradicts its position here. (*See* D.I. 442, 5–6.)

<sup>5</sup> To the extent UTC prevails before the Supreme Court and the ’793 patent is revived, Liquidia would simply pay damages. UTC, by its own account, will not suffer a precipitous drop in sales because Yutrepia<sup>TM</sup> will not be automatically substituted for Tyvaso.



COO, Michael Benkowitz, told UTC shareholders that even upon Liquidia competition, UTC will still achieve its goal of a “\$4 billion run rate by mid-decade[,]” and “Tyvaso will continue to be the preferred agent[.]” (Ex. 3 (UTC at TD Cowen Health Care Conference), at 3, 6.) UTC’s allegations of irreparable harm are proven untrue by Dr. Rothblatt’s and Mr. Benkowitz’s public statements to UTC shareholders explaining Liquidia’s entry into the market will not disrupt UTC’s status quo.

### **III. Granting UTC’s Motion to Stay Will Only Prolong the Irreparable Harm Suffered by Liquidia**

UTC further insists that its manufactured harm outweighs any inequities that might be suffered by Liquidia as a stay will merely “maintain the status quo.” (D.I. 485, 3.) This is simply not true. The “status quo” is that UTC’s patent is invalid and Liquidia is free to provide its product to consumers.

Continuing to prevent the launch of Yutrepia<sup>TM</sup> will only prolong the irreparable harm already suffered by Liquidia. The ’793 patent has been invalid since July 19, 2022, yet Liquidia has been enjoined from launching its product until this Court entered its Rule 60(b) Decision on March 28, 2024. (D.I. 480.) UTC has enjoyed over a year and eight months of exclusivity based solely on an invalid patent. There is no reason it should continue to benefit at the expense of Liquidia and consumers. Furthermore, if a stay is granted, Liquidia would remain the only drug manufacturer that would be precluded from obtaining final FDA approval based on the ’793 patent. *Mendenhall*, 26 F.3d at 1583 (“when the rest of the industry is not impeded by the patents, it seems manifestly unjust to . . . hold[] appellants liable and impair[] their ability to compete”). Thus, the balance of hardships tips heavily in Liquidia’s favor here.

Moreover, public interest favors denying UTC’s request for a stay. Yutrepia<sup>TM</sup> would offer pulmonary hypertension patients a new and improved product to treat this chronic, life-threatening disease, and promote competition, ultimately resulting in reduced patient costs. In addition to the benefits patients would receive, there is strong public interest in keeping UTC’s market exclusivity within its scope: “A patent by its very nature is affected with a public interest” and “[t]he far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.” *Blonder-Tongue*, 402 U.S. at 343 (quoting *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 816 (1945)). UTC has already enjoyed exclusivity over the inhaled treprostinil market based on an invalid patent and granting a stay would effectively operate as a continuation of this undeserved benefit, which would be detrimental to the public interest.

For these reasons, Liquidia respectfully requests that this Court deny UTC’s request to stay the Rule 60(b) Decision.

Respectfully submitted,

/s/ Nathan R. Hoeschen

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (by hand delivery)  
All counsel of record (by e-mail)

# EXHIBIT 1

# REFINITIV STREETEVENTS

## EDITED TRANSCRIPT

UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

EVENT DATE/TIME: MAY 03, 2023 / 1:00PM GMT

## OVERVIEW:

UTHR reported 1Q23 revenues of \$0.5b.

MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

## CORPORATE PARTICIPANTS

**Dewey Steadman** *United Therapeutics Corporation - Head of IR*

**Leigh Peterson** *United Therapeutics Corporation - SVP of Product Development*

**Martine A. Rothblatt** *United Therapeutics Corporation - Founder, Chairman & CEO*

**Michael I. Benkowitz** *United Therapeutics Corporation - President & COO*

## CONFERENCE CALL PARTICIPANTS

**Andreas Argyrides** *Wedbush Securities Inc., Research Division - Analyst*

**Ashwani Verma** *UBS Investment Bank, Research Division - Director of Americas Equity Research & US Specialty Pharma Analyst*

**Eun Kyung Yang** *Jefferies LLC, Research Division - MD & Senior Equity Research Analyst*

**Hartaj Singh** *Oppenheimer & Co. Inc., Research Division - Research Analyst*

**Jessica Macomber Fye** *JPMorgan Chase & Co, Research Division - Analyst*

**Joseph John-Charles Thome** *TD Cowen, Research Division - MD & Senior Research Analyst*

## PRESENTATION

### Operator

Good morning, and welcome to the United Therapeutics Corporation First Quarter 2023 Earnings Webcast. My name is Danielle, and I will be your conference operator today. (Operator Instructions)

Please note this call is being recorded. I would now like to turn the webcast over to Dewey Steadman, Head of Investor Relations at United Therapeutics.

---

### Dewey Steadman - United Therapeutics Corporation - Head of IR

Thank you, Danielle, and good morning. It's my pleasure to welcome you to the United Therapeutics Corporation First Quarter 2023 Earnings Webcast. Accompanying me on today's call are Dr. Martine Rothblatt, our Chairperson and Chief Executive Officer; Michael Benkowitz, our President and Chief Operating Officer; James Edgemon, our Chief Financial Officer and Treasurer; and then Pat Poisson, our Executive Vice President of Technical Operations; and finally, Dr. Leigh Peterson, our Senior Vice President of Product Development.

Remarks today will include forward-looking statements representing our expectations or beliefs regarding future events. These statements involve risks and uncertainties that may cause actual results to differ materially. Our latest SEC filings, including Forms 10-K and 10-Q, contain additional information on these risks and uncertainties, and we assume no obligation to update these forward-looking statements.

Today's remarks also may discuss the progress and results of clinical trials or other developments with respect to our products. These remarks are intended solely to educate investors and are not intended to serve as the basis for medical decision-making or to suggest that any products are safe and effective for any unapproved or investigational uses. Full prescribing information for these products are available on the products' websites.

Now I will turn the webcast over to Dr. Rothblatt for an overview of our first quarter 2023 financial results and the business activities of United Therapeutics. Martine?

---

## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thank you, Dewey. Very excited to welcome everyone to another great quarter at United Therapeutics. We are thrilled to continue on course toward our mid-decade goals of 25,000 patients being treated for pulmonary hypertension and the doubling of our revenue run rate. This quarter, we moved toward those goals with double-digit revenue growth from first quarter '22 to first quarter '23. And that also includes, by the way, nearly 40% growth in our main growth driver, which is Tyvaso.

I think our double-digit growth rate remains a solid forecast even with the possibility of new FDA approvals of sotatercept or Liquidia. The reason is that sotatercept has not even been tested in our main growth market of Group 3 pulmonary hypertension. Indeed, systemic drugs are generally contraindicated there due to them causing V/Q or ventilation-perfusion mismatch. In the disease sotatercept was tested in, Group 1 pulmonary arterial hypertension, we expect it to be complementary to either our Orenitram, Tyvaso or Remodulin products. So we don't forecast a realistic threat from sotatercept to our growth.

(inaudible) Liquidia, if approved, also does not challenge our projected double-digit growth. It's because it's not a generic product, but is instead a strongly differentiated drug device product requiring 65% more drug to even match Tyvaso's effect based on their own clinical trial data.

Also exciting to report this quarter is the robust progress in our pipeline. We are spot-on target to fully enroll our current big Phase III trials by the end of next year, each of which have their own billion-dollar potential. In other words, the pipeline [shown] embeds more than double our current total revenues, and then there is the aforementioned organic doubling of our revenues from our existing products already commercialized and now entering the market, such as Tyvaso DPI, Remunity and our new Orenitram dose titration kits.

I'm also very excited to report big news on the use of capital front. We have allocated \$0.5 billion to a new Tyvaso DPI manufacturing facility in Research Triangle Park, North Carolina, with 50,000 patient capacity. And by the way, this is in addition to our existing nearly \$100 million allocation of capital to our new clinical xenotransplantation facility in Virginia.

By the way, speaking about transplant, I'd like to thank the dozens of our shareholders and other stakeholders who sent me Amy Silverstein's superb story of her heroism in the face of heart transplants and immunosuppressants. In that vein, I wanted to take a moment to update everyone on what we at United Therapeutics are doing to effectuate Amy's quest.

In our own lab center company, we reprogrammed differentiated cells from patients back to stem cells called iPSCs, or inducible pluripotent stem cells. By the end of this year, we'll be creating iPSCs from 2 patient donors every single month. In our own labs, we differentiate cells into different types of cells needed for cellularizing different organs, such as lung, including stromal cells and epithelial cells and different types of alveolar cells.

In our own labs, we grow differentiated cells in 3D chambers into the billions of cells needed to cover each organ. Indeed, in our own labs over the past 3 years, we have produced about 2 trillion cells every year.

Also in our own labs, we cellularize our organ scaffolds with the cells that we have expanded. Indeed, last month, we achieved a kind of (inaudible) level of proof of concept for one of our own cellularized lungs, provided a pig model with the level of (inaudible) considered acceptable for human lung transplants.

Again, in our own labs, we produce this time under GMP conditions about 500 lung scaffolds every year and are now working on 3D printing kidney and liver scaffolds in partnership with 3D Systems. In short, Amy's vision of an immunosuppressant-free organ transplant is realistic for this decade, the 2020s.

Here at United Therapeutics, we expect to have patient-derived, stem cell-differentiated autologous lungs, kidneys and livers in the clinic within 5 years. Hearts could also be done. No immunosuppressants would be needed because the transplanted organs will have the same DNA as the patient. So it is really the best of times here at United Therapeutics with record revenues, another \$0.5 billion quarter, record pipeline potential, \$2 billion-plus opportunities and record deployment of capital and business expansion.

## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

At UT, our mantra is go big or go home. We are going big on pulmonary hypertension. We are going big on pulmonary fibrosis. And we are going big on creating an unlimited supply of transplantable, tolerable organs. Mike Benkowitz, our President and Chief Operating Officer, will now give you a deeper dive into the business. Mike?

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Thanks, Martine, and good morning, everyone. We're pleased to report yet another quarter of meaningful growth for our treprostinil business. And as Martine said, we're really excited to have quarterly revenues of more than \$500 million for the second time in our company's history.

As usual, I'm going to provide some color around what we're seeing with respect to each of our treprostinil products: Tyvaso, Remodulin and Orenitram. For Tyvaso and Tyvaso DPI, underlying physician and patient demand for Tyvaso remained exceptionally strong in the first quarter as we continue to grow our Tyvaso active patients at a clip consistent with the patient growth trends for the prior 3 quarters.

We saw a record number of referrals, which is what we call prescriptions, and new patient starts during the first quarter. We also continued to increase the breadth and depth of the Tyvaso prescriber base. Since the PH-ILD launch in 2021, we have now doubled the number of Tyvaso prescribers. That's our breadth metric. And in terms of prescribing depth, I've mentioned on prior calls that our key metric here is the number of prescribers with 3 or more Tyvaso patients.

I'm really happy to report that we've also doubled the number of prescribers in this category. The 3-plus Tyvaso prescribers now represent about 40% of all prescribers, which means we still have an opportunity to expand depth, which should pave the way to further accelerate Tyvaso growth over time.

The first quarter performance for Tyvaso saw the usual early year seasonality with respect to patient discontinuations due to insurance changes and also as usual, discontinuations returned to normal levels in February, March and in April. Importantly, discontinuations for Tyvaso DPI continue to run well below that of nebulized Tyvaso, reflecting patient satisfaction with Tyvaso DPI. So overall, we believe the underlying strength of the Tyvaso business is great.

Looking at first quarter revenue, as I said in the past, due to the nature of our business, we regularly encourage investors to look at longer-term revenue trends compared to quarterly revenue fluctuations. With that said, there were 3 main factors that impacted Tyvaso revenue in the first quarter, given that we're essentially in the middle of 2 product launches within the Tyvaso franchise, PH-ILD and then Tyvaso DPI.

First, and as we discussed last quarter, our specialty pharmacies are still rightsizing orders for the correct DPI and nebulized mix. In the third quarter of last year, specialty pharmacies made significant orders of nebulized Tyvaso in anticipation of increased PH-ILD demand without fully appreciating the potential for Tyvaso DPI demand.

Moving to the fourth quarter of last year and the first quarter of this year, we saw unexpectedly strong demand for Tyvaso DPI relative to nebulized Tyvaso. And the specialty pharmacies needed to reduce its nebulized inventory, which reduced Tyvaso revenue well under patient -- well under actual patient demand in the fourth quarter of 2022 and the first quarter of this year.

Second, we're seeing a higher level of PAP utilization for Tyvaso DPI than we expected. We believe this is a short-term phenomenon and will subside to a large degree when the Medicare changes that are part of the Inflation Reduction Act go into effect starting next year.

Finally, due to the incredible demand for DPI and the fact that we launched immediately upon approval without building inventory, we have not been able to allow specialty pharmacies up to their contractual minimum inventories each month. Based on our DPI demand trends and forecast, this is something that could persist for the balance of the year. Having said that, we are taking steps to increase DPI production capacity in both the short and medium term.

First, our partner, MannKind, is activating a second production line and additional kitting capacity from which we expect to see increased DPI supply as soon as this quarter. Second, and in parallel, MannKind is also on track to significantly expand manufacturing capacity in the first half of

## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

next year to support up to 25,000 Tyvaso DPI patients a year. And finally, as Martine mentioned, we have initiated a construction project to build a new UT-owned and operated Tyvaso DPI manufacturing facility. That facility is intended to provide enough capacity to support an additional 50,000 DPI patients per year and with expansion capacity for up to 75,000 DPI patients.

Turning to Remodulin. This business continues to be incredibly resilient, even though it's faced a generic competitor for almost 4 years now. We saw the second highest number of referrals for Remodulin in the first quarter. And after a small dip in active patients following the generic launch of a subcutaneous version of Remodulin, our active patients are back to pre-generic levels. Remunity continues to gain traction in the market as it is the only subcutaneous pump widely available for new Remodulin patient starts, with Remunity representing over half of our monthly subcu Remodulin shipments during the quarter.

Finally, Orenitram had a very solid quarter, achieving record number of patients on therapy and record revenues. We launched a 90-day titration kit during the first quarter, which simplifies dosing and titration for new patients. While still early, physician and patient feedback has been very positive around the convenience of these new kits. There continues to be a lot of buzz in the physician community around the EXPEDITE data we top-lined last October, demonstrating that prostacyclin induction with Remodulin can lead to double the average Orenitram dose when patients shift to oral therapy and in a shorter period of time as compared to patients who do not have a Remodulin induction. We expect to publish a peer-reviewed manuscript detailing the study in the coming months.

To wrap up, we're very pleased with the overall treprostinil business, led by the incredible demand for Tyvaso DPI, and we believe we're on our way to hitting our goal of a \$4 billion revenue run rate. With that, I'll turn the call back over to Martine to start the Q&A session.

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thank you so much, Mike. Those were terrific insights into every one of the products. Really appreciate that color that you shared with everyone. Operator, could you please open the phones, and I will sort the questions to the person most appropriate for answering them.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) The first question comes from Joseph Thome of TD Cowen.

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**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

Mike, I know you mentioned that the Tyvaso DPI discontinuations are a little bit lower than what you were seeing with the nebulized Tyvaso. Maybe what are the expectations for the Tyvaso DPI average time on therapy versus what you were seeing with the nebulizer? And as we see sotatercept potentially launching maybe next year, do you expect the Tyvaso time on therapy could actually increase as these patients kind of continue to do maybe better than they did without sotatercept? Or would they intend -- maybe ramp down their prostacyclin use? How do you expect that to kind of play out?

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Mike, looks like Joe directs his question to you.

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## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. Thanks, Joe. So I think overall, we're really encouraged by the lower level of discontinuation rates with Tyvaso DPI. And we do think that, that augurs well for increased time on therapy. To put a number on that, I think it's still a little early to kind of say definitively what that's going to be. But certainly, patient satisfaction has been really high with Tyvaso DPI. I think it's led to better adherence, better compliance and that leads to patients doing better, and then that will ultimately lead to patients staying on therapy longer. So I think your premise, your hypothesis that time on therapy will increase with DPI over time is absolutely right. And that's something we're certainly expecting.

Similarly, I think sotatercept probably helps in that regard as well. If you look at the underlying data in the sotatercept study, 70% of the patients in that study were on a background prostacyclin. So as Martine said in her opening comments, we think there's a lot of complementary effects between prostacyclin and sotatercept. And so we would expect that when sotatercept is launched into the market, that will continue and patients will experience a nice benefit between the 2 products as well as the other products on background therapy and should continue to lead to increased time on therapy.

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**Operator**

Next question comes from Hartaj Singh of Oppenheimer.

**Hartaj Singh** - *Oppenheimer & Co. Inc., Research Division - Research Analyst*

Nice update, everybody. Just had a question on Orenitram and the EXPEDITE study. I know at ERS last year in Barcelona, really big updates there and educating the patient-physician community. It seems like at ATS this year, again, you will kind of delve into that. If you can just talk to us a little bit about what the patient flow is. Are patients mostly starting on Remodulin and then going over to Orenitram? Or are they still starting on Orenitram -- or what's the breakdown? And then how can we expect sort of that to benefit Orenitram going forward? I know it already is, but could that add even more going forward?

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Great question, Hartaj. Mike, I think you'd, again, be the best person to address that question.

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. Thanks, Hartaj, for the question. So in terms of kind of the mix of patients between starting de novo on Orenitram and transitioning from Remodulin, I think it's roughly, call it -- 2/3 roughly, 2/3 of patients are starting de novo on Orenitram right now. And as I mentioned in my comments, I think the fact that we've got that titration -- new titration kit, I think that's going to continue to help patients titrate up on Orenitram, starting de novo, and then the balance are transitions from Remodulin.

I still believe that there will be patients that will start de novo on Orenitram over time once we really fully, I think, take advantage of the EXPEDITE data. But I also think it's true that Tyvaso DPI is proving to be so convenient for patients, and it's almost sort of your gateway drug to prostacyclin. So I think over time, you're going to see a higher number -- higher percentage of patients initiate prostacyclin therapy on DPI, even over the orals, both Orenitram and selexipag.

And so the thing that we really like about the EXPEDITE data and then the ARTISAN study, which we've talked about on prior calls, is it's an opportunity to take these maybe functional class III patients or even IV patients in the case of ARTISAN, start them on Remodulin, get their hemodynamics down -- closer to normal levels. And then you can flip them over to Orenitram and really use Orenitram as their maintenance drug and continue to titrate up as you need. And if they -- if over time, they decline, then you can obviously switch them back to Remodulin.



## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

But we really see that as sort of a key position for Orenitram as we move forward over the next several years. And in some, it really just kind of speaks to the flexibility of treprostinil and the fact that we've got these different delivery options. And so it really just, I think, allows us to kind of meet the patient -- the physician where the patient is in their disease progression.

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Great. Thanks so much, Mike. That was really beautiful, the way you were able to describe that with ARTISAN and EXPEDITE and the whole rapid transition to oral. We're able to get patients into a stable equilibria, if you will, with their pulmonary artery pressures down around, I would say, below 40 millimeters of mercury. And there's like an increasing volume of data out there, well over a dozen scientific papers that have shown that patients with pulmonary hypertension who are managed in this kind of potential, well between 30 and 40 millimeters of mercury, are able to achieve very long-term survival, 10, 20 years out to the limit of the papers -- of the data that the papers had access to. And those are papers by independent physicians, not from us.

So we really believe that our initial mission of the company of being able to keep patients with pulmonary hypertension living with pulmonary hypertension instead of dying from pulmonary hypertension has been very largely achieved with the combination of parenteral prostacyclin to rapidly get their pressures down and then oral prostacyclin, Orenitram, to be able to keep them stable in the long term.

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**Operator**

The next question comes from Jessica Fye of JPMorgan.

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**Jessica Macomber Fye** - *JPMorgan Chase & Co, Research Division - Analyst*

On the plans to increase capacity for Tyvaso DPI, that sounds pretty bullish with respect to the anticipated demand trends there. And it sounds like you're seeing nice net patient adds as well. But can you just confirm whether there's any capacity constraint on DPI right now that's at all limiting to patient adds? Or is it that you're keeping up with patient demand and then in the near term, the capacity is maybe just keeping the specialty pharmacies from reaching target inventory levels?

And just related to that, I think you said Tyvaso net patient adds were in line with the past 3 quarters. Can you just remind me what that run rate was that you're tracking in line with?

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Okay. Thanks so much for the questions, Jess. There were several questions there. So let me start with the production expansion questions. And then, Mike, if you could queue up your responses to the rest of the questions that Jess asked there.

So Jess -- so we are pretty bullish on our forecast for Tyvaso DPI. And the maximum capacity of the MannKind facility up in Danbury, Connecticut will be -- by the beginning of next year will be for 25,000 DPI patients. So we'll be entering '24 with a capacity for 25,000 patients.

Now as I mentioned in my introductory remarks, our company's goals for the middle of the decade are being able to treat 25,000 pulmonary hypertension patients. So if a large proportion of those 25,000 patients are on Tyvaso DPI, which is, I think, reasonable, then it would be like, well, where is the production capacity for the go big on pulmonary fibrosis? Where is the production capacity for what we think the pulmonary fibrosis market will be?

Well, best as we can tell, we expect the pulmonary fibrosis market to actually be for Tyvaso DPI even larger than the pulmonary hypertension market. So we would need more than an additional 25,000 patient capacity for the pulmonary fibrosis market. And indeed, the market research and the disease-modifying hypotheses that we have for Tyvaso DPI in pulmonary fibrosis is such that we could easily expect to have 50,000

## MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

pulmonary fibrosis patients being treated in addition to the 25,000 mid-decade pulmonary hypertension patients. So that's the reason why we need to start now deploying a substantial amount of capital to build this brand-new Tyvaso DPI production facility in Research Triangle Park, North Carolina.

As Mike mentioned, even that facility, even though its launch capacity will be 50,000 patients, it will have a surge capacity to go up to 75,000 patients. So we think between the 25,000 at MannKind, the 50,000 in North Carolina, the surge to 75,000 in North Carolina, as we enter the 2026 time frame, we then have a capacity to support 75,000 to 100,000 DPI patients, which would cover our needs for both Group 1 pulmonary hypertension, Group 3 pulmonary hypertension, idiopathic pulmonary fibrosis and additional forms of pulmonary fibrosis that go under the rubric of proliferative -- progressive pulmonary fibrosis, which in fact, we are embarking on the other additional Phase III trial for.

So Mike, with those comments in terms of the production capacity, can you answer the other questions that Jess had?

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**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Absolutely. So Jess, I think your question around your first -- first part of your question was around sort of patient demand versus SP demand to build up their inventory. So we're definitely in the category of the latter. So we're not having to halt or delay patient starts on DPI. We're making enough to meet the patient demand.

I think the issue that I was referencing in my opening comments is typically, specialty pharmacy, they have an algorithm for figuring out how much -- how they order every month. They typically try to order up to have, call it, roughly 2 months of inventory on hand and then over the course of the month, they'll get down to about 30 days. So they generally like to keep at least -- always be in a position where they have at a minimum 30 days of inventory on hand. So due to the demand, we're not able to kind of meet that need on the part of specialty pharmacy.

Like I said, we have some additional production capacity coming online as soon as this quarter. That will start to open things up a little bit. But I think really, as we're continuing to grow over the balance of the year, we're probably going to be in this situation where they're not going to be able to order up to the levels they're accustomed to ordering up to until, as Martine said, we get the significant expansion next year to get up to 25,000 patients.

Second part of your question was just sort of the average, I guess, the run rate in terms of patient adds. So if you look back over the last -- this quarter or the prior 3 quarters, it's kind of averaged out to around 500 patient adds per quarter on Tyvaso, and that's between both DPI and nebulized.

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**Operator**

The next question comes from Eun Yang from Jefferies.

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**Eun Kyung Yang** - *Jefferies LLC, Research Division - MD & Senior Equity Research Analyst*

I have a question on TETON trial. So we are expecting data in 2025. So based on the Phase III INCREASE trial, subgroup of patients with underlying IPF, we saw benefits on FVC up to 16 weeks. So TETON trial is a 52-week time point. So do you expect benefits on FVC to continue to increase to 52 weeks? And then can you comment on powering assumptions for the TETON trial?

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thanks. Nice to hear your questions. I think it will be best to have Dr. Peterson -- she is in charge of running the TETON trial, answer your questions.

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MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

**Leigh Peterson** - *United Therapeutics Corporation - SVP of Product Development*

Yes. Thank you for your question. Yes, so in fact, the INCREASE study, indeed, the main study, the placebo-controlled study, was 16 weeks, as you mentioned. However, we do have an open-label extension study of the INCREASE data where we've looked to see how the patients do over the longer period of time, including the 52-week time period. And we still see benefits of patients on Tyvaso in the INCREASE population. So we feel confident that, that will translate to the longer period in the TETON studies.

And as far as the TETON study, they are definitely powered, I mean, we have 90% power to detect the difference that we've seen in the INCREASE studies with regard to absolute FVC. So we have sufficient power to see the difference over the 52-week period. So again, we feel confident on that.

**Operator**

The next question comes from Andreas Argyrides of Wedbush Securities.

**Andreas Argyrides** - *Wedbush Securities Inc., Research Division - Analyst*

Congrats on the quarter. When thinking -- so quickly, first, what's the status of the organ manufacturing programs? And when can we expect [first] program to enter clinical trial? And then how should we think about spend when it comes to organ manufacturing? And I have one follow-up.

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Okay. We won't be able to take your follow-up, and Andreas, thanks for the congrats on the quarter. Your line broke up a little bit, but I think the gist of the question was to get an overview of the organ manufacturing situation and when we expect results of the organ manufacturing to enter into clinical trials. And I think you asked something about the capital associated with other spending.

So the organ manufacturing program is a broad, multifaceted, multiple shots on goal program. So it won't be really realistic to give an overview of everything beyond the really exciting things I mentioned this morning, in response to Amy Silverstein's passionate arguments, that part of our organ manufacturing program is strongly focused on organs that would not require immunosuppressants. In other words, autologous organs that are manufactured with the cells downstream from a patient's own donated cells.

And within different laboratories at United Therapeutics, we currently produce iPSC cells. In other words, we reprogram PBMCs and another differentiated cells from patients back into stem cells. We then used techniques proprietary to the company to then differentiate those stem cells into the different types of cells that we would cellularize organs with.

Other programs at other laboratories within United Therapeutics are based on allogeneic cell lines that we are able to MHC segment. So patients could expect a much lighter immunosuppressant load than if they were just taking kind of an average donor organ.

And then let me get to your question about the clinical trial. So the organs we have closest to clinical trials are our xenohearts and xeno-kidneys. These are hearts and kidneys from donor animals that have been grown under the equivalent of good manufacturing practices conditions, what are called pathogen-free conditions. And they have 10 genetic modifications that we believe will allow them to surmount hyperacute and acute rejection with no more than the normal commercially available immunosuppressants today and be able to continue on to a long-term duration in the recipient's body with the management of chronic rejection as is done today with allografts.

So those organs are currently in what's called by the FDA a pivotal preclinical program. That means it's the last preclinical program before going into a human study. And that program is -- hopefully, we will be able to complete that program by the end of '24 and be able to then enter into the first clinical trials in '25. So that would be kind of a bottom line answer to your question, that the first manufactured kidneys and hearts, hopefully, knock on wood, should be able to enter into clinical trials in '25.

MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

#### Operator

The next question comes from Ash Verma of UBS.

**Ashwani Verma** - *UBS Investment Bank, Research Division - Director of Americas Equity Research & US Specialty Pharma Analyst*

I had one on sotatercept impact. So the feedback that we've heard from physicians indicates that Merck's product positioning and payer reception can have an important bearing on what part of your portfolio may get impacted. In your view, does that matter? And like what is the assumption that you have on competitors' pricing in line of therapy positioning?

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Okay. Thanks for the questions, Ash.

(technical difficulty)

like a frontline question, then Mike -- I mean, answer, then Mike will give you more of a definitive answer. But as I noted in our introductory remarks, we don't see sotatercept having any effect whatsoever on the growth guidance that we've provided for our company. And the reason for that is a lot of people are not completely clear that there are 2 different diseases that are treated with drugs such as ours that sound very similar and it's easy to get them confused.

So the disease that sotatercept was tested in and the disease that all of our drugs are approved for, all of our non-cancer drugs are approved for is called Group 1 pulmonary arterial hypertension, and the acronym is PAH. A different disease is called Group 3 pulmonary hypertension or just Group 3 PH. Sotatercept has never been tested, at least anything published that we're aware of, in Group 3 pulmonary hypertension. The only drug approved for Group 3 pulmonary hypertension is Tyvaso, including Tyvaso DPI.

And as Mike described very well, most of our growth in the coming years, we expect to come from Group 3 pulmonary hypertension. So by definition, sotatercept cannot have any effect on that growth trajectory whatsoever.

In addition to that, within the Group 1 pulmonary arterial hypertension, where we do continue to have growth across our franchise, I think Mike mentioned we had our highest quarterly sales of Orenitram ever, we expect sotatercept to be complementary. And Mike, would you like to expand on that?

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. I'll just kind of pick up right there, which is, I think I said in response to an earlier question around this, we definitely look at sotatercept as complementary to our drug and the other drugs that are currently on the market to treat Group 1 PAH. It's another pathway. So now we have a drug to treat 4 different pathways associated with pulmonary arterial hypertension. If you look at the -- as I said, if you look at the data in the sotatercept trial, 70, 7-0, 70% of those patients were on prostacyclin therapy. So clearly, there appears to be a complementary or synergistic effects between prostacyclin and sotatercept.

So we think that all of the drugs will continue to be used. I think some physicians that we've talked to have talked about this sort of four corners approach of treating PAH, so you have a drug to treat each of the 4 pathways. How that gets sequenced and -- in the grand scheme of things, doesn't really matter because I think it's still a progressive disease. There was nothing in the sotatercept data really that suggest that it's a cure or even a disease-modifying agent. I know there were some speculation that, that might be the case, but I don't think that's borne out in the data.

MAY 03, 2023 / 1:00PM, UTHR.OQ - Q1 2023 United Therapeutics Corp Earnings Call

So clearly, patients are benefiting from it, but I think it's a combination with the other drugs. And so we think over time, it's another drug that physicians can add to their treatment armamentarium, but it doesn't appear to be something that's going to replace or displace our products.

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thanks so much, Mike. And thank you, operator, and everybody, for joining our first quarter conference call. Great work, Dewey Steadman. We'll be presenting at various and sundry health care conferences during the balance of the year, and we look forward to seeing you there and providing additional insights and color on United Therapeutics' business. Operator, you can disconnect the call.

#### Operator

Thank you for participating in today's United Therapeutics Corporation earnings webcast. A rebroadcast of this webcast will be available for replay for 1 week by visiting the Events & Presentations section of the United Therapeutics Investor Relations website at [ir.unither.com](http://ir.unither.com).

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# EXHIBIT 2

# REFINITIV STREETEVENTS

## EDITED TRANSCRIPT

UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

EVENT DATE/TIME: FEBRUARY 22, 2023 / 2:00PM GMT

## OVERVIEW:

Co. reported 4Q22 results.

FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

## CORPORATE PARTICIPANTS

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**James C. Edgemon** *United Therapeutics Corporation - CFO & Treasurer*

**Leigh Peterson**

**Martine A. Rothblatt** *United Therapeutics Corporation - Founder, Chairman & CEO*

**Michael I. Benkowitz** *United Therapeutics Corporation - President & COO*

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**Hartaj Singh** *Oppenheimer & Co. Inc., Research Division - Research Analyst*

**Jessica Macomber Fye** *JPMorgan Chase & Co, Research Division - Analyst*

**Joseph John-Charles Thome** *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*

**Justin Hovsep Simonian Phillips** *Morgan Stanley, Research Division - Research Associate*

## PRESENTATION

### Operator

Good morning and welcome to the United Therapeutics Corporation Fourth Quarter and Full Year 2022 Earnings Webcast. My name is Devin, and I will be your conference operator today. (Operator Instructions) I will now turn the webcast over to Dewey Steadman, Head of Investor Relations at United Therapeutics.

### Dewey Steadman - United Therapeutics Corporation - Head of IR

Thanks, Devin, and good morning. It is my pleasure to welcome you to the United Therapeutics Corporation Fourth Quarter and Full Year 2022 Earnings Webcast. Accompanying on today's webcast are Dr. Martine Rothblatt, our Chairperson and Chief Executive Officer; Michael Benkowitz, our President and Chief Operating Officer; James Edgemon, our Chief Financial Officer and Treasurer; Pat Poisson, our Executive Vice President of Technical Operations; and Dr. Leigh Peterson, our Senior Vice President of Product Development.

Remarks today will include forward-looking statements representing our expectations or beliefs regarding future events. These statements involve risks and uncertainties that may cause actual results to differ materially. Our latest SEC filings, including Forms 10-K and 10-Q, contain additional information on these risks and uncertainties. We assume no obligation to update these forward-looking statements.

Today's remarks may also discuss the progress and results of clinical trials or other developments with respect to our products. These remarks are intended solely to educate investors and are not intended to service the basis for medical decision-making or to suggest that any products are safe and effective for any unapproved or investigational use. Full prescribing information for the products are available on our website.

And United Therapeutics executives will participate in 3 investor conferences in March. First, Michael Benkowitz will participate in a fireside chat at the Cowen Healthcare Conference on Tuesday, March 7. Dr. Martine Rothblatt will participate in a fireside chat at the Oppenheimer Healthcare Conference on Monday, March 13, and our Chief Medical Officer, Gil Golden will participate in the JPMorgan Napa Valley Biotech Forum on Tuesday, March 21.



## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

Now I will turn the call over to Dr. Rothblatt for an overview of the fourth quarter and full year 2022 financial results and business activities of United Therapeutics. Dr. Rothblatt?

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thank you, Dewey, and good morning, everyone. I feel very excited to lead this call because we have so much positive news to report about 2022.

In fact, I -- reflecting back on the past few years, this is actually the best year United Therapeutics has ever had. And it augurs even more, I think, positively to what we're going to see coming up in 2023, 2024 and 2025.

Let me hit a few highlights. First, 2022 was our highest revenue year ever. Second, 2022 was our most profitable year ever. Third, 2022 was our highest operational cash flow year ever. And fourth, we ended 2022 with more patients on our treprostinil medicines than ever before.

I think you have to agree with me that these are fantastic results. And now I'd like to give a few indications of why I think that as great as these results are, they are not laurels for us to rest upon but instead a launching pad for yet greater results in 2023, 2024 and 2025.

In fact, the patient uptake of our new Tyvaso DPI medicine has been so rapid that we can project a doubling of our revenues by 2025. This doubling of revenues is helped by the unique nature of each of our medicines including Tyvaso DPI. For example, Tyvaso DPI is the only inhaled treprostinil product that enables deep lung penetration via high-resistance low-flow device.

Another example, our Remodulin product is the only parenteral prostacyclin delivered by the small, easy, super accurate Remunity device. The differentiated aspects of Remodulin has allowed us revenues to remain steady at about \$0.5 billion a year through the past 3 years running.

Our Orenitram product is also very unique because it is the only titratable oral prostacyclin product. We currently expect it's 1/3 of \$1 billion a year revenue to continue growing as physicians become aware of the results of our recently released EXPEDITE study. That study showed Remodulin patients can be switched directly to Orenitram. And Orenitram will soon be joined by new products from our pipeline.

In the field of pulmonary arterial hypertension, we expect to complete our Phase III trials of ralinepag by 2025. That will enable the first once-daily dosing of a prostacyclin pill in the pulmonary hypertension field.

In the field of pulmonary fibrosis, we expect to complete our Phase III trials of Tyvaso by 2025 as well. That will, we hope, create the first disease-modifying treatment for pulmonary fibrosis, a true landmark in the field.

And in the area of transplantation we hope to commence clinical trials of manufactured organs within the next few years. That would be a major contribution to ending so many deaths on the organ transplant list and unfortunately, even more deaths from end-stage organ disease off the transplant list.

In summary, our business, our patient count, our pipeline is growing longer and faster than ever before. 2022 marked the continuation of that growth factor into 2023. We have achieved a very nice balance of growth and strength. We intend to continue building on this platform in the years to come.

To provide now some additional, very median I think, extremely exciting details of how we are continuing to build on this platform, I'd like to introduce our President and Chief Operating Officer, Michael Benkowitz. Mike?

## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Thanks, Martine, and good morning, everyone. From a commercial standpoint, as Martine said, 2022 was a phenomenal year for us. We're extremely pleased with the progress of the Tyvaso DPI launch as referrals starts and active patients for both Tyvaso and Tyvaso DPI are among the best that we've seen to date.

We were also very excited to achieve our goal of doubling the number of Tyvaso patients following the PH-ILD approval in early 2021. This was a goal that Unitarians across the organization rallied around and supported. So we're really proud and appreciative of everyone's hard work over the last couple of years to help us reach this milestone.

Importantly, reaching this goal reinforces to us the impact that Tyvaso and Tyvaso DPI are having not only in helping patients with PH-ILD treat this serious progressive disease for which there are no other available options, but also the impact Tyvaso DPI will have in PAH. With the simple convenience of a small inhaler that fits in the palm of the patient's hand and an elegant ease of use following the simple mantra of open, load, inhale. We believe Tyvaso DPI will meaningfully expand the use of inhaled treprostinil in both indications.

The Tyvaso DPI inhaler device developed by our partner, MannKind, is able to efficiently deliver treprostinil deep into the lung and one breath per cartridge using less active ingredient to the nebulizer reference. The convenience and efficacy of our DPI device, coupled with Tyvaso's known tolerability profile has us well positioned to expand our reach in PH-ILD and to move the use of treprostinil therapies like Tyvaso DPI and PAH even earlier than IP receptor agonist like selexipag.

We're seeing this play out with our prescribers as evidenced by several positive trends. Since the PH-ILD launch, we've increased the total number of Tyvaso prescribers by about 70%, an increase by almost 60%, the number of prescribers with 3 or more patients in their practice.

This last point is an intra marker we look at to gauge product support. We have found that once a physician has at least 3 patients on one of our products, they tend to become what we call supporters and start using the product much more frequently and regularly.

We're also making headway with traditionally loyal selexipag prescribers. Of the top 100 selexipag prescribers, 70% have now written Tyvaso DPI and 50% of those have written 5 or more prescriptions. From a revenue standpoint, we're very pleased with how the quarter and the year wrapped up for Tyvaso, but there are a few key points I want to highlight.

First and most relevant to the fourth quarter of 2022 is that we're still in a launch mode for Tyvaso DPI and even for the PH-ILD indication for that matter. As such, our specialty pharmacy distributors are still rightsizing product orders based on estimated underlying patient demand, both in total and between Tyvaso nebulized and Tyvaso DPI. Therefore, our distributors are placing orders more frequently than their once or twice a month historical cadence. And these new ordering patterns did impact the timing and size of product orders and thus our product revenues during the quarter.

Second, we're also building Tyvaso DPI inventory as we're launching a product. So our distributors are not yet able to order a sufficient product to reach contractual inventory levels per their usual practice. We expect over the next several quarters, these 2 factors will normalize, and our specialty pharmacy distributors will shift back to a more historical type cadence of product orders. For these reasons and the usual historical seasonality to our business that we have discussed on prior calls, we think annual revenue trends are a better lens through which to view and evaluate our business.

The last thing I want to touch on with Tyvaso is our patient assistance program or PAP. Patient utilization of our program -- of our PAP program for Tyvaso DPI which is covered under Medicare Part D and has high patient co-pays, has been higher than anticipated, including by many PH-ILD patients who were on the nebulizer and nPAP last year and has since transitioned to DPI.

We anticipate that this will be a short-term phenomenon and that many of these patients will be covered under their Medicare Part D plan starting in 2024 and continuing into 2025, once changes to the Part D provisions of the Inflation Reduction Act begin to go into effect.

## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

Turning to Orenitram. We see continued momentum for Orenitram as we ended the fourth quarter with the highest number of patients on therapy since its launch. We're also excited about the recent top line EXPEDITE data we press released in October of last year that demonstrated that prostacyclin induction with Remodulin can lead to double the average Orenitram dose when patients shift to oral therapy compared to patients who do not have a Remodulin induction.

Following up on this top line data, we plan to present additional details on EXPEDITE at scientific meetings this year, along with a peer-reviewed manuscript detailing the study in the second quarter.

And finally, we continue to be pleased with the performance of Remodulin in the U.S. as the fourth quarter was one of our highest referral quarters ever. The Remunity pump for Remodulin is gaining momentum with approximately 1/3 of subcutaneous patients now on Remunity especially as Remunity is the only subcu pump widely available for any patients to treprostinil therapy.

So to wrap up, after reaching our goal of doubling the number of Tyvaso patients, we're confident in our ability to double our annual revenue run rate for approximately \$2 billion today to \$4 billion by the end of 2025. We expect continued Tyvaso and Tyvaso DPI uptake in both PAH and PH-ILD to drive most of our near-term revenue growth, supplemented by Orenitram growth through the expedite protocol and other research and supported by continued Remodulin resilience. With that, I'll turn the call back over to Martine.

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**Martine A. Rothblatt** - United Therapeutics Corporation - Founder, Chairman & CEO

Michael, thank you so much for providing that wealth of detailed information supporting this great growth vector we have going here from 2022 into 2023, '24, '25.

Operator, feel free to open up the lines to any questions now.

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## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) Our first question comes from Jessica Fye with JPMorgan.

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**Jessica Macomber Fye** - JPMorgan Chase & Co, Research Division - Analyst

I have 2, if that's okay. First, can you provide some of the assumptions, specifically around Tyvaso and Tyvaso DPI to help underpin your target to roughly double your revenue run rate for the overall company by the end of 2025.

And then second, just following up on Michael's comments in prepared remarks, I was hoping if you could elaborate a little bit more on that comment about the utilization of the PAP program for DPI being higher than anticipated among PH-ILD patients who transitioned to DPI. Is that to say that because of the higher out-of-pocket in Part D in the short term that they're receiving free drug? And how should we reconcile that with, I think, what was anticipated to be a bit of a tailwind in 2023 from PAP patients transitioning on to reimbursed product this year?

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**Martine A. Rothblatt** - United Therapeutics Corporation - Founder, Chairman & CEO

Yes. Thank you, Jess, and good morning. Good to hear your voice this morning. Generally, we try to like limit to one question for questioner because there are so many people in queue. But because your 2 questions are in a sense kind of like a tag team question, one way close into the next, Mike, I'll kind of ask if you can handle both questions.

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## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Yes. So I think, Jess, your first question around the assumption, the underlying assumptions for our confidence in the growth of Tyvaso in both PAH and PH-ILD is, in some ways, it's a little bit of a math -- kind of a math exercise, but also just I think -- I think just the excitement and enthusiasm we're seeing around DPI.

So if you think about in the PAH or the WHO Group 1 market, there's about, I mean, roughly 50,000 patients in the U.S. diagnosed with PAH, still and shockingly and sadly, it's probably only about, I would say, about 30% to 35% of those patients are on a prostacyclin. And there's a lot of reasons for that, and a lot of it comes down to the fact that the delivery mechanisms for prostacyclin are -- they're not terribly convenient. But I think that is changing on Tyvaso DPI. So we feel very confident that we will be able to -- with the convenience of the DPI inhaler to be able to expand the use of prostacyclins in the PAH market meaningfully.

So I think we feel like even though it's a crowded market, even though Tyvaso has been out there, we still think that there's a lot of opportunity within the WHO Group 1 market to grow the use of prostacyclin and particularly Tyvaso.

And then a similar story, but maybe a little bit easier on the PH-ILD side because there, you have a market that's conservatively 30,000 patients with no other approved therapy. And so we've roughly tapped into about 10% of that over the last couple of years, and we think we have another other 90% available to us. So we still feel like we have a lot of runway there to grow with Tyvaso. And again, I think just with the convenience of DPI, it's going to get easier for doctors to prescribe that drug for those patients that have PH-ILD.

And then shifting to your second point on the PAP. So yes, so the issue is that we had patients in PH-ILD, patients on Medicare and our PAP program for 2021, 2022, expected a lot of those to roll over starting in 2023. And a lot of those have started to roll over in 2023. It's not as high as -- the number that are rolled over, it's not as high as we expected for a couple of reasons.

One is I think at the end of the third quarter, I think we reported that there were about 700-ish patients in the PAP program. So some of those discontinued which we expected. Some of those even after becoming -- even with the CMS coverage, still qualified for PAP. And so they stayed in PAP. And then as I said in my prepared remarks, we did have a number of patients that transition to DPI between the end of the third quarter and the beginning of the first quarter. And so with the higher co-pays and Part D, they were then eligible to remain in PAP.

So I think we still had about half, slightly more than half of those patients convert over. I think they're still -- they're kind of working through the system, but it's a little bit less than we were expecting, I think, when we had the call in the third quarter.

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Those are great answers. Jess, one just additional shade of color I could add on top of Mike's remarks with regard to your question as to what kind of parameters can I provide to provide greater assurance about the doubling of revenues by the end of '25 is the uptake of Tyvaso DPI has been dramatic. And as Mike mentioned, he provided some metrics, for example, the very high number of selexipag prescribers who have not previously prescribed on Tyvaso now prescribing Tyvaso DPI.

So when we achieve the doubling of our patients on Tyvaso over a period of just 18 months, I can't really overemphasize what an important metric that is. Just to give you kind of a sense, Tyvaso was approved 10 years ago. So it took like 10 years to get up to a certain level of patient penetration for this drug and then in under 2 years, it doubles. I mean that's -- it's an unmistakable sign in addition to the steps that Mike shared with you that this product is going to penetrate very, very rapidly.

Now while one might think that in an area such as PH Group III, which has been penetrated by no pulmonary hypertension medicines like, oh, these are all just like people dying of thirst and just going to just slap up this new medicine right away, the reality in a disease like pulmonary hypertension is that it just doesn't happen like that. Instead, it's a very kind of blocking and tackling exercise of physician by physician, center by center working through all of the rigorous of talking to the right payers and getting the payers to understand the right procedures and going through all the procedures and the pre-approval, diagnoses, requirements, the catheterizations and all of these things.

## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

So while we did create like special teams focused on PH Group III before we launched into that indication, in the field of pulmonary hypertension, one year of kind of preparation is sort of like nothing compared to how much activity is needed to build a bulk of patients. So now that 1 year is more than 2 years behind us, we've now had a year of actual practice, okay, you can actually put these patients on medicines.

As Mike referred to, the payer aspects, especially with regard to Medicare, we're just very, very recently resolved favorably in our direction. And so the -- it's just you have to like first have not just 1 year and not just like there wasn't like a waiting bolus of patients in Group III just waiting for a launch, you have to like develop this market and really kind of till the soil for a number of years. We've now done that, and we're experienced in those clinics and it's this reason why we think out of those 30,000 PH Group III patients. Fortunately, none of them have been touched by pulmonary hypertension treatment that we can rapidly grow our numbers of patients at the same rate that we've been growing them for the past year with this doubling of the number of patients on Tyvaso and thereby reach a number of total treprostinil patients, something that would be in the 20,000 that would correlate when you multiply that times the reimbursement per patient to the \$4 billion per year.

And of course, it's important. In addition to this, not to be losing revenue from Remodulin or Orenitram. But not only are we not losing revenue, we're solidifying our hold on the Remodulin revenues as Mike referred to the very rapid penetration that the Remunity pump has made and we're growing our revenues in Remodulin -- in Orenitram as a result of the EXPEDITE study that Mike described. So we feel that doubling revenues in 3 years is really a very doable too.

Operator, next question, please?

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**Operator**

Our next question comes from Terence Flynn with Morgan Stanley.

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**Justin Hovsep Simonian Phillips** - *Morgan Stanley, Research Division - Research Associate*

This is Justin Phillips on for Terence. Just one question for me. I was wondering if you could provide any details today on the Tyvaso trends for January and February.

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Sure. Mike, would you like to take that?

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**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. I'm not going to get into too much detail in terms of previewing the quarter. I mean, I think what I can tell you is and really I have got about a month of data behind us, but I can tell you that the trends in terms of referrals, that's what we call prescriptions for Tyvaso in January are very strong, had like a record level for January.

So -- and at least what I'm seeing through kind of there's a lag on the February data, but February is continuing that. So again, I think we're really pleased, just to echo what Martine said, I think we're really pleased with the uptake of generally and specifically with DPI.

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**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thank you, Mike. That's so nice to hear. Record January referrals after a record year, fantastic. Next question, please.

## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

**Operator**

Our next question comes from Hartaj Singh with Oppenheimer & Company.

**Hartaj Singh** - *Oppenheimer & Co. Inc., Research Division - Research Analyst*

Just a quick question on a slightly different topic with your plan to potentially double revenues by 2025, you still got the Tyvaso IPF Phase III trial reading out around then which is positive. Martine sense another nice little runway there. Could you maybe just go over -- remind us again if Gil is on the call, the data behind that, your certainty around that project? And then just some basic sizing of the market.

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Sure, Dr. Singh, so happy to hear your voice this morning, and thank you for asking a science question. We love those questions best of all. We have on our call, Dr. Leigh Peterson, and she is our Chief Scientist for the program, and she's also running the TETON clinical trials. People often wonder why they are named TETON, and it's because Dr. Peterson is from Wyoming. So it makes perfect sense. And Leigh, if you could provide Hartaj with some of the scientific reasons why we feel very confident that the Phase III trials of Tyvaso in IPF are rightly sized and that the endpoints are rightly chosen.

**Leigh Peterson**

Yes, sure. Thank you for the question. As you know from the results of our INCREASE study, we had an exploratory endpoint, which was forced vital capacity. And that was really -- for the PH-ILD population, it was really a safety assessment in the study but it turned out, we actually saw an improvement of that endpoint in patients on Tyvaso and so -- relative to placebo.

And so between the results of this study, increase in PH-ILD patients as well as quite a few -- quite a bit of evidence in the literature of in vitro in nonclinical studies that Tyvaso or treprostinil does have an impact on fibrosis.

It's very reasonable that we would be able to have a positive impact in an IPF population. And so using the statistics and the treatment effect that we saw, an increase in specifically IPF patients, we were able to do sample size calculations in order to predict that we would have a successful study with a sufficient p-value to get approval. And we're actually doing 2 studies, one TETON 1 study in the U.S. and Canada as well as TETON 2, which is outside of U.S. and Canada in order to -- in each of those studies, about 400 patients -- almost 400 patients, and enrollment is going well as expected.

And as Martine -- that we expect to read out in around the 2025 time frame of both of those studies. They both have an FVC endpoint again, same as what we saw, a positive sense in INCREASE. And we have a year-long follow-up period. We've also had some published results of the INCREASE. You might remember that the randomized part of the study an INCREASE was 16 weeks, but we continue to follow patients -- those patients in a long-term open-label extension study. And so we've been collecting long-term FVC data as well, which looks promising and also gives us confidence that the TETON studies will be successful, but to be determined in 2025 time frame.

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Well, thank you so much, Leigh. And I just want to and toot your horn just for a moment to the hundreds of people on the call that there was similar skepticism as to whether or not Tyvaso could work in Group III patients and you proved that it could. And I believe your results were published in the New England Journal of Medicine. So congratulations again. Next caller, please.

## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

**Leigh Peterson**

Thank you. Yes, they were.

**Operator**

Our next question comes from Ash Verma with UBS.

**Ashwani Verma** - UBS Investment Bank, Research Division - Director of Americas Equity Research & US Specialty Pharma Analyst

I have one. So for Tyvaso, was there any inventory buildup in 3Q that bind you down mostly in 4Q or do you think inventory is still at an elevated level during 4Q? I think you mentioned that specialty distributors are still rightsizing the orders.

**Martine A. Rothblatt** - United Therapeutics Corporation - Founder, Chairman & CEO

Thank you, Ash. Thank you for that question. Fortunately, we have our Chief Financial Officer, on the phone, James Edgemond. And James, if you could perhaps help Ash with the inventory question.

**James C. Edgemond** - United Therapeutics Corporation - CFO & Treasurer

Yes. Thank you, Martine. Thank you for your question. I think there's kind of 2 ways to answer. One is Michael addressed and talked about the Tyvaso and Tyvaso DPI ordering patterns in his prepared remarks. And I think if you look at B as part of the answer, the other products there was no unusual ordering or inventory activity and our specialty pharmaceutical distributors were in line with their contractual requirements on inventory. So hopefully, that provides you insight in terms of your question this morning. So thank you, and back to you, Martine.

**Martine A. Rothblatt** - United Therapeutics Corporation - Founder, Chairman & CEO

Thank you, James. Operator, next question please.

**Operator**

Our next question comes from Joseph Thome with Cowen and Company.

**Joseph John-Charles Thome** - Cowen and Company, LLC, Research Division - MD & Senior Research Analyst

We're going to be seeing the full mark of sotatercept Phase III data at ACC in about 11 days. And I was just curious how you see a potential future sotatercept launch impacting the PAH market broadly and maybe how this is reflected in that 2025 revenue run rate guidance that you announced.

**Martine A. Rothblatt** - United Therapeutics Corporation - Founder, Chairman & CEO

Yes. Thanks for the question. So it's really like super speculative to provide any kind of a meaningful answer to the question because we don't know what the regulatory time frame is going to be for sotatercept. So it's all but impossible to give you any kind of accurate sense.

I will say that our revenue forecast is agnostic with regard to whether or not sotatercept is approved or not. In other words, we will remain confident about achieving the doubling of our revenues by 2025 without regard to its launch. There -- it's a very large and diversely treated patient population. Changes in treatment patterns are relatively slow and cautious especially other than frontline treatments such as like ETRAs or PD5s. So I'd be very,



## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

very skeptical that you would see an impact of sotatercept on United Therapeutics revenue profile or product uptake across the board, whether it's Remodulin, Tyvaso, Tyvaso DPI or Orenitram.

More broadly, the experience has been that when new agents have been introduced into the market, it has grown the market for all of the existing patients. It's kind of like a market growth thing. You saw this with, for example, back in the day when we launched Remodulin and J&J's precursor Actelion launched bosentan, the treprostinil revenues did not shrink. In fact, they grew and then later on, when PD5s were introduced, the market for ETRAs, and treprostinil did not shrink. In fact, it grew, it grew quite a bit. And this has been just a continuous process, and it harkens back to the landmark number that you should keep in your mind that Michael Benkowitz mentioned in his remarks was 50,000, that's 5-0 thousand. That's the number of patients diagnosed with pulmonary hypertension. And all of these drugs have just like scratched the surface of being able to really treat the patients and get them back to a New York Heart Association Functional Class I or even Functional Class II level.

So there is so much robust room for growth and improvement in pulmonary hypertension. We at United Therapeutics, welcome any new agent that can help the health of the pulmonary hypertension patient population. And by the way, all that is with respect to WHO Group I pulmonary hypertension. So everything I just said, then you've got this other huge pool that Dr. Peterson opened up with her New England Journal article, WHO Group III, 30,000 patients, that's 3-0 thousand, of which the only approved treatment right now is our Tyvaso drug.

And I think sotatercept, I would love to see another good drug to help people with pulmonary hypertension. I don't think it's going to have any effect on our revenue growth.

Next question, operator, and we'll have to cut it after that due to coming to the end of time.

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**Operator**

Our final question comes from Andreas Argyrides with Wedbush Securities.

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**Andreas Argyrides - Wedbush Securities Inc., Research Division - Analyst**

Congrats on a great year. Just a quick one here on Tyvaso DPI. Are you still seeing more rapid up taking new patients versus transition? And what is the split between new and transition patients?

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**Martine A. Rothblatt - United Therapeutics Corporation - Founder, Chairman & CEO**

A very good question. Mike, can you give us our final answer on the call?

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**Michael I. Benkowitz - United Therapeutics Corporation - President & COO**

Sure. Yes. So it's -- I think it's -- I have to go back to look, I haven't look at it in a couple of weeks, but I think it's still weighted towards new patients in terms of DPI. I mean the transitions are coming. It's just as I think I said on the last call, I think what physicians are doing is they're waiting until patients come in for the regular checkup. So they're kind of coming -- they are coming in at a healthy clip, healthier than what we were seeing and I think that will continue through the course of the year.

And so I fully expect at the end of the year, those patients that want to transition to DPI will transition to DPI. So it's certainly a kind of a point of emphasis for our sales team. And certainly, as I said -- certainly, I think the physicians are aware of it and as those patients come in and they decide that the patient is eligible to transition, they'll move them over.



## FEBRUARY 22, 2023 / 2:00PM, UTHR.OQ - Q4 2022 United Therapeutics Corp Earnings Call

**Martine A. Rothblatt** - *United Therapeutics Corporation - Founder, Chairman & CEO*

Thank you, Mike. Well, to wrap up the call, we are tremendously excited about 2022. This is the year that we hit our \$2 billion revenue run rate that has been our goal for really much of the past several years. And we are even more jazzed and more pumped by the fact that the \$2 billion level, makes it very clear to us that \$4 billion is achievable with all of the products that we are currently marketing and explaining to physicians, the scientific and medical benefits of.

And then beyond that, as Hartaj indicated in his question, we have a whole another slew of type -- of products coming out of our Phase III pipeline, particularly a whole new disease indication, pulmonary fibrosis and then on top of that, a best-in-class treatment for pulmonary hypertension, which would be Ralinepag. So 2022 was amazing, a huge kudos to everybody on the team for achieving it. 2023 is looking even better. And with that, operator, you can close out the call.

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**Operator**

Thank you for participating in today's United Therapeutics Corporation Earnings Webcast. A rebroadcast of this webcast will be available for one week by visiting the Events and Presentations section of the United Therapeutics Investor Relations website at [ir.unither.com](http://ir.unither.com). Have a good day.

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# EXHIBIT 3

# REFINITIV STREETEVENTS

## EDITED TRANSCRIPT

UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

EVENT DATE/TIME: MARCH 05, 2024 / 5:50PM GMT

## OVERVIEW:

## Company Summary

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

## CORPORATE PARTICIPANTS

**James C. Edgemond** *United Therapeutics Corporation - CFO & Treasurer*

**Michael I. Benkowitz** *United Therapeutics Corporation - President & COO*

## CONFERENCE CALL PARTICIPANTS

**Joseph John-Charles Thome** *TD Cowen, Research Division - MD & Senior Research Analyst*

## PRESENTATION

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

44th Annual TD Cowen Healthcare Conference. I'm Joe Thome, I'm one of the senior biotech analyst here on the team at TD Cowen. And it's my pleasure to have with me today the team from United Therapeutics. We have President and COO, Mike Benkowitz and CFO and Treasurer, James Edgemond. Thank you both for joining us.

## QUESTIONS AND ANSWERS

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

So maybe just to start things off, congrats on the record revenues in 2023. Maybe just give us a brief overview of the company's recent progress and your outline goals for the rest of this year?

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. Thanks, Joe, and thanks for hosting us today. Before I get started, my lawyers would want me to say something about forward-looking statements. So there you go. You guys can check out our public filings with the SEC to look at the risks and uncertainties associated with that.

So yes, 2023 was really a fantastic year for us, and I think it sets us up well for the future. What we're really focusing on, really last year, this year and in the future is executing on what we've called the 3 ways of growth that we've been talking about the last few investor conferences and at our last earnings call. So the first wave is what we call the foundational wave, which is really about commercial execution with respect to our already approved products, continuing on the recent growth trajectory from a revenue standpoint with those products.

The second wave is the innovation wave and really there, what we're focused on is development and then eventually commercialization of ralinepag in pulmonary arterial hypertension, PAH and then Tyvaso in IPF and PPF or progressive pulmonary fibrosis.

And then the third wave is what we call a revolutionary wave and that's our organ manufacturing business. And so we now have a really well-rounded multiple shots on goal approach to developing an unlimited supply of commercial organs in the kidney, heart, lung and liver space.

So that's really, I think, at a high level, what we're focused on, specifically with respect to 2024, it's really 4 things. One is to continue, like I said, continued revenue growth in the -- along the same trends that we saw in the last couple of years, 20% plus. We're looking on the innovation side, we're looking to complete enrollment in the ralinepag study and the 2 IPF studies with Tyvaso.

On the revolutionary side, where we expect to complete the preclinical work for the xenokidney and this quarter actually and then hopefully get a meeting with the FDA later this year that will lead to commencing a clinical trial as early as 2025. And then we're also excited with one of our recent acquisitions, Miromatrix, to begin the first human clinical trial with a bioengineered organ, which is the miroliverELAP.

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

And the company has previously indicated, hoping to achieve a \$4 billion run rate by the end of 2025. I guess what are sort of the key aspects of the commercial franchise that get you there? And maybe what proportion of that is going to come from? Tyvaso versus the rest of the franchise?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Yes. So we said \$4 billion run rate by mid-decade. So 2025, 2026 in that time frame. And really, if you just kind of draw a line or extend the growth over the last couple of years, we're well positioned to do that. The lion's share of that growth will come from Tyvaso, particularly (inaudible) associated (inaudible) where we are currently the only approved therapy for that disease. Continue to make good traction in identifying those patients that are good candidates for that therapy.

But we also expect to, at a minimum, maintain Remodulin revenues. Though even with that said, last year, we actually had modest growth in Remodulin on our U.S. business, which is, we think, pretty phenomenal given that we've had a generic competitor for 5 years now. And then we expect to run (inaudible) to continue to grow on the heels of the expedite data, which we published a couple of years ago. And then we have a new study with Remodulin to Orenitram transitions, which is our ARTISAN study.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Okay. And obviously, the Tyvaso expansion into PH-ILD has been a huge investor focus and good for the top line. Can you tell us a little bit how many patients have you treated with PH-ILD or rather how penetrated into this market are you? Just kind of overall, where is the franchise there in terms of patient finding and how penetrated drug is?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Yes. So for PH-ILD, if you look at the epi data, it's a pretty broad range. I think the epi data suggests anywhere from 15% tied to 85% of the 230,000 ILD patients have or will get pulmonary hypertension. We've tended to really kind of focused on the low end of that range, 15%. So we look at the market as being around 30,000. I think you talked to various KOLs. I'd say it's significantly higher, but 30,000 is a good number for us to start with. It's almost as large as the PAH market. And as I said earlier, we're the only approved product in that space. So that's really kind of how we think about the size of the market right now.

And then in terms of penetration, we're in kind of the low double-digit range there, kind of in that 10% to 15% range and then continue to make progress every month, every quarter, every year and growing that patient base. And so we've undertaken, I think, several steps, which I'm sure I'm going to talk about, to continue to increase that penetration, educate those ILD physicians about pulmonary hypertension, steps they need to go through to screen those patients. And then at that point, they have a decision about whether they want to treat or refer to a PAH clinic.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

And maybe along that point, the company did expand the Tyvaso sales effort and sales force in 2023. Maybe if you can just remind us how large an expansion this was maybe what was driving this decision, if anything different than what you just highlighted? And maybe when will we start to see the impact from that expansion in revenues?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Yes. So I mean the expansion actually, I would say, the expansion of our field-based teams actually started about 12 to 15 months ago. So it was broader than just the sales representatives. We increased our medical science liaisons. We increased a team that we call our regional nurse specialists.

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

So these are nurses that we employ to go in and work with nurses in the office and teach them how to use our products, how to titrate, how to manage side effects.

And then we also deployed last year a team of what we call field reimbursement managers and the goal of that team or the objective of that team is, again, to go work with offices, particularly new prescribers and help them navigate the reimbursement process. We're filling out the referral form with how to write an appeals letter. So educating them on that whole process, because it's a pretty complex process for those practices that are used to dealing with our therapies.

And then the second half of last year, we augmented the sales team. So on a numbers basis, the sales team, we increased like say by maybe 25%. But really, I think the impact is going to be greater than that, because in addition to increasing the size of the teams, we also realign promotional priorities. So we now have a group of sales representatives that are only calling on ILD doctors and talking about PH-ILD. So the magnitude impact of that is greater than 25%, because they're now spending 100% of their time talking about PH-ILD.

And so really, what I think was just a recognition -- the reason we did it was just a recognition by us that we needed to provide more support, there was more opportunity out there that we maybe weren't optimizing. I think we felt like the -- maybe the sales representatives were spread a little (inaudible) of why they were reaching all the prescribers, the frequency by which they were able to talk to them and educate them wasn't where we thought it needed to be.

So that expansion on the sales force started middle of last year. You have to go through the hiring process, the training. So really, they deployed in earnest 1st of this year. And so it'll probably take a couple of quarters, really, I think, to start to see traction on the benefit of that. So as we get to the second half of the year, we would expect to see the payoff from that investment.

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**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. And the company does typically highlight seasonality in the fourth quarter and first quarter, at least relative to Q2, Q3. But obviously, in the last quarter, we did see quarter-over-quarter growth in Tyvaso specifically. Did this kind of buck the trend? Or is there underlying seasonality still in Tyvaso? Or what was sort of behind that growth?

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**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Yes. So there's a natural seasonality to our business. We talked about this on prior calls. It's really a function of when we look -- at least when you look at the revenue line, because we have 2 specialty pharmacies, right? So it's a closed channel really 2 customers. They have an algorithm for which they can determine how much they're going to order, that's tied predominantly to shipping data in the quarter. So when you get into the fourth quarter, you really lose 2 to 3 weeks with the holidays in terms of shipping days. On the physician patient side, there's also fewer clinic days. So fewer days for physicians to see the patients.

And then we see this phenomenon often typically between Thanksgiving and Christmas where, just because of the complex nature of our therapies, patients will often wait until after the first of the year. So we may have referrals and prescriptions coming in. The starts may not occur until after the 1st of the year. And so that happens really across what we see that to varying degrees across all of our products. And so that -- we saw that in Q4 on a relative basis. But particularly with Tyvaso, we were able to grow through it, right, just because of the volume that was coming through.

Now the interesting thing is we didn't see it the prior year when you're looking at the revenue line, if you look at the underlying drug product going out to patients, we actually grew through it last year, too. The challenge we had last year, as you recall, is we had this inventory adjustment, because we were -- we had the nebulizer. We launched DPI. And so the specialty pharmacies were having to adjust their inventory levels to draw down their nebulizer inventory while they were stocking up on the DPI side. And so when you look at the revenues last year, it looks a little wacky. It looks like we actually had a down quarter, but the underlying metrics were still really strong. And so we saw that again this year as well.

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. And then maybe on the capacity with the DPI is all of that now behind us, nothing related to that? And then maybe if you can give a high-level update on the capacity expansion, just in preparation for IPF and PPF successful?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Sure. Yes. So the capacity issues that we were running into last year are behind us. MannKind, who's our partner and is manufacturing DPI for us, made some enhancements to their production lines, so they're able to increase production in the middle part of last year. And then as we move to the second half of the year, where we're seeing the benefit of that. We're bringing online actually this month, a kitting line down in North Carolina, so to keep this at a high-speed kitting line, because that has been sort of our last bottleneck to the extent there was one is that we were using a third party and they weren't moving as they were limited on how fast it could move. So now we've got a high-speed kitting line.

So those issues are behind us and the specialty pharmacies are able to order, rely on fleet within their contractual limits. We're starting to build up a little bit of inventory ourselves and that will just continue as we move into the balance of the year. Not to mention MannKind is adding 2 high-speed filling lines. And so that will increase our capacity when that comes online later this year, that will increase our capacity to support up to 25,000 patients a year.

And then as we think about IPF, just to kind of round that out, we have a new production facility that we broke ground on last year in North Carolina to further manufacture DPI and that will have a capacity for an additional 50,000 patients. And that should come online right around the time that we launch into IPF.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. Maybe on the Tyvaso DPI uptake in the field yesterday on our physician panel, the doctor indicated, there's actually still quite a bit of use of the nebulized product, especially during maybe dose titration and getting patients up to speed. Maybe overall, can you tell us where are people using the DPI? Are they converting their new patients? And are you seeing the same level of use of nebulizer to DPI? Or how is it fitting in?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Yes. So if you look at our revenues the last few quarters and the last couple of quarters, I guess, where we've broken out DPI and nebulizer, I think it's roughly a 60-40 split in terms of DPI. And that's tracking well when we look at the patient level data in terms of the mix of patients. I would say that new prescriptions coming in, new referrals coming in are more along the lines of 70-30. So over time, you would expect -- we would expect that the revenue is going to reflect that, and I think it will.

So in terms of where the DPI is coming from, initially, it was a lot of transitions of patients on nebulizer that wanted the benefit or the convenience of the DPI. That's largely played out at this point. So patients that were on the maintenance dose of neb and wondering to transition to DPI have transitioned over. And so DPI now is really -- I think it's really kind of starting to solidify itself as sort of frontline prostacyclin therapy in PAH and then obviously in PH-ILD which we've talked about.

So those are -- on the PHI there's going to be prostacyclin-naïve patients. Could also -- we are also seeing some transitions from the orals. So selexipag, for instance, if patients aren't doing well. That might be the next stop, depending on where the patient is in their disease progression.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Okay. And then we do have an FDA decision coming up for Merck sotatercept later this month. Maybe if you could talk just a little bit about how you expect sotatercept to impact the PAH business, I guess just the landscape overall and then -- and as it relates to your top line as well or any of the product usage?

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Yes. I think over the, I mean, the medium to long term, we don't really see it impacting our business in a material way. And it's another therapy, they have very good clinical data. It's great for patients. I think as you look at -- you peel back the onion or the covers and look at their data and where it was used, how it was used. I think the things that we're really encouraged about is that 70% of the patients were on a background prostacyclin, like a Remodulin or Orenitram. So it does seem to suggest that those 2 products work well together.

So it's -- the other thing I would say is it's not a cure, it's not a replacement for prostacyclin. I think patients are still going to need prostacyclin. Increasingly, polytherapy is becoming the norm in PAH. And so you have the various pathways you cover with a PDE5 and the [RRA] prostacyclin, and this is the fourth pathway. So I think it's additive to the products that are out there. I don't really see it as being a replacement for any one product, including ours.

And I think the nice thing for the patients and us from a financial standpoint is if the drug is working really well, then sensibly the patients are going to live longer, they're going to stand our therapies longer. So that's kind of how we see it's another the tool of the toolkit for the physicians to use. But long term, we don't really see it impacting our business.

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

Perfect. And obviously, there's some ongoing litigation with Liquidia. So we're not going to ask specifically about those decisions. But I guess how do you see Liquidia as a potential competitor? Is that factored into your business model at all? Or maybe why is the DPI, even if liquidity were to come to market saying PAH could be the preferred agent?

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Did you say why would Liquidia become the -- I think I believe -- we believe Tyvaso will continue to be the preferred agent for very -- I mean the big one is that we've got 2 years of patient data, thousands of patients on the product. The patients are -- satisfaction level is incredibly high both by the physicians and by the patients. And so they have that experience with our product, which is incredibly helpful.

I think -- we think the convenience of our device as a differentiator. Ours is one (inaudible) per session. Their's 2. Ours doesn't require cleaning. Their's does. We don't have a max label dose. And so we just think, all in all, the patients and the physicians are going to prefer our product. We think the other thing that's attractive about our devices are just what's called a low-flow device and so that means that it requires less patient effort to actually breed the drug.

And then as a result of that, that property or that characteristic. The drug is actually getting deeper into the lungs. So what you see with a high flow device, which is what their device is. So we think all in all, the totality of the characteristics of our device are going to be preferred by physicians and patients.

And then on the payer side, you were in these discussions right now with payers and kind of working that out. But I think we're feeling increasingly confident that there's not going to be preference, so it's going to be a level playing field. So it's really going to be up to the patient and the physician, and we feel confident about how we're going to do there.

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

Perfect. And then you mentioned earlier the Tyvaso in IPF and PPF yesterday on the panel, again, the physicians are really impressed with the increased data and sort of even in the placebo patients when you give Tyvaso, you do see that recovery in FVC. I guess what in the data package has resonated best with physicians? And maybe what -- can you update us on the status of the IPF and PPF program?



MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. Well, I think the main thing is the FVC improvement that we saw in the increased data, the physicians have been really excited about it. This trial has been enrolling incredibly fast. We were able to actually increase the sample size last year without sacrificing any of our time lines. So I think both trials now are -- there's 2 trials. There's a U.S. trial. There's a rest of world trial, both our sides are around 575 patients. And we expect to complete enrollment this year in both trials. It's a 52-week study. So we'll get the last patient in end of -- towards the end of 2025 and then expect to have a readout soon thereafter.

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

Perfect. And can you talk a little bit about the addressable patient population in IPF, PPF? I guess, where would the drug fit in into this treatment paradigm?

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Sure. So for IPF in the U.S. We see that as a patient population of about 100,000 patients. And in the TETON trials, patients can be on background therapy. So it will be additive to the existing therapies that are out there. In PPF, it's we think it's roughly 60,000 patients in the U.S.

So again, another unmet need that where patients can benefit from Tyvaso. And then in the case of IPF, I think we'll actually do this in PPF, but IPF for sure, we designed that to support our European filing. So we would expect to file in Europe and launch there soon after getting FDA approval.

**Joseph John-Charles Thome** - *TD Cowen, Research Division - MD & Senior Research Analyst*

Perfect. Maybe jumping over to the oral prostacyclin side of the business. I know we've discussed previously how some of the Orenitram data maybe hasn't or kind of was impacted by COVID in terms of relaying that to physicians, which maybe didn't get the full impact of that data set out to the market. I guess how is Orenitram launching now? How big do you think this could get? And then we'll dive into ralinepag after that.

**Michael I. Benkowitz** - *United Therapeutics Corporation - President & COO*

Yes. So I mean, it's interesting with Orenitram, because if you look at the clinical data for all of our products, it's far and away our best data. I mean you've got clinical works team, you've got improvement in some of the risk factors that physicians look at for patients in PAH. You've got an indication of survival at a cost that's actually less expensive than (inaudible).

So the whole package there is -- the value prop for Orenitram, we think is really high. I think the challenges that we see sometimes with Orenitram is its titration is good and bad, right? I mean it's good that you can titrate up. It's also a little bit more complicated to communicate to the patient. And then you have just the normal side effect things that happen with the prostacyclin. And so I think the words getting out on the data. I think what we have seen or what we found is that the -- I think the ideal place to use Orenitram is after Remodulin.

So that was the whole point behind the expedite study. So these aren't Remodulin patients that are sitting on Remodulin for years and transitioning over. Although we do have patients like that. But the idea with the expedite study was to take a patient that you would otherwise start on Orenitram, start them with Remodulin, get them up to a good dose over a period of weeks. Some doctors have done it in days, but really the study was to do it over a number of weeks, then be able to transition the patient over to a higher level dose of Orenitram with fewer side effects.

And so I think we're finding increasingly that the doctors are using that protocol to start patients on Orenitram. So that's really starting to get traction. And I think that's why we're seeing continued growth on Orenitram and that should continue.

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

And then you have ralinepag in clinical development. I guess, how would this fit into the treatment paradigm as it is right now? Would this be sort of a direct swap for Orenitram? Obviously, we talked about dose titration just now and sort of some of the data you have in relation to Remodulin. But could all of that be essentially seen as also captured in ralinepag? Or do you see it in a different setting?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

I think it remains to be seen. I think we'll see what the trial bears out in terms of the efficacy titration, how high (inaudible) and patient outcomes. And I think we certainly see it as a direct competitor to selexipag is the same class of drug, IP receptor agonist. And so -- and with the once-daily dosing, we think that that's going to be an attractive option or alternative to selexipag. And then like I said, depending on the data, we'll see how that competes with Orenitram and there are properties of prostacyclin that patients benefit from over an IP receptor agonist. I think regardless of how this plays out, there's always going to be a role for Orenitram.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. Maybe on the xenotransplantation side, the company has indicated that they're now in pivotal preclinical studies for the xenotransplantation therapy. Maybe just at a high-level progress on that side of things? And what are sort of the pivotal preclinical studies that you need ahead of moving into the clinic?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Going to let my friend, James, answer a question.

**James C. Edgemon** - United Therapeutics Corporation - CFO & Treasurer

Yes. Thank you. So overall, we are continuing to make very good progress. And as lead Dr. Leigh Peterson said on the last earnings call, we are in discussions with the FDA in terms of satisfying their request for data in baboon studies. And so we're progressing those final studies this year, continuing conversations with the FDA with the goal next year, Joe, early of 2025 to get an IND approved for human clinical trials in xenotransplantation. So that's kind of the goal. And I think the progress has continued. And as an organization, we're very excited, and we're doing what the FDA has asked at this point.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. And as it relates to the xenotransplantation side of the business. Can you remind us the current footprint that you do have in terms of facilities and maybe what spend was associated with the current (inaudible)?

**James C. Edgemon** - United Therapeutics Corporation - CFO & Treasurer

Sure. So what we announced a few weeks ago was we did a ribbon-cutting grand opening for a facility in Christiansburg, Virginia that we will use for growing the pigs that will be used for human clinical trials. And what we've said publicly is that facility was about \$75 million that we established, we finished construction, and that will -- we're starting to get ready again to play into the time lines of working with the FDA to start human clinical trials in early or 2025. And that should be a good footprint for us to get to where we need. And then from there, we would expand into the commercial designated pathogen-free facilities.

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

And that is one of the questions that we do get is how large of an expansion you would need to do for commercial opportunities. So what is the company thinking in regards to that? How many facilities would you need? And maybe what are the major derisking steps? Obviously, you mentioned the derisking steps to get to where you're at right now. But in order to turn on that additional investment, what would you want to see, I guess, in the clinic?

**James C. Edgemon** - United Therapeutics Corporation - CFO & Treasurer

Yes. Thank you. So we've talked publicly about in terms of these areas, we do want to initially start, and I'll talk about when. But with the commercial DPF facility and we've targeted a range for a cost to be between \$1 billion and \$2 billion. I think it will settle out somewhere in between and you can average use an average of \$1.5 billion. What we are anticipating and planning to do is once we get an IND approved with the FDA, we will evaluate kind of the protocol there and start to understand how the clinical trial can roll out.

What we will do at that point because it's going to take about 3 years to build a commercial-scale designated pathogen-free facility, but we want to make sure we're doing it in a very thoughtful and methodical way. So that the human clinical trial moves forward, we're understanding that process and then starting to construct the facility. But we're going to do it in a way where we can watch the clinical trial and we can start to spend money because we won't downstroke a check in day 1 for \$1.5 billion on average, but that will happen in time, and we want to be very thoughtful, methodical about how we spend the money and making sure that we understand the clinical trial and where it's going so that we can make sure at the end of that clinical trial, we're in a situation and a position to be able to supply transplantable organs to those in the.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. And on the last quarterly update, the company did announce that the FDA has cleared the IND for the miroliver ELAP program. Maybe just overall. Can you discuss the rationale for the Miromatrix acquisition? And what would an initial trial look like post this IND?

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Sure. Yes. So the Miro we did -- we actually did 2 acquisitions last year, Miromatrix, and IVIVA. And really, the goal there, the objective there was really to kind of round out our organ programs. That gives us some more shots on goal. So we had been -- we had the xeno programs that we've talked about. We have a regenerated lung program, and then we have an autologous lung program on a 3D-printed scaffold that we've been working on. So this gives us another shot -- more shots on goal in the kidney and the liver. So that was really the rationale behind doing those.

In terms of the miroliver ELAP trial, I think the important thing there is that it serves the first bioengineer organ that's going into clinical trial. I think as a product, it's probably a niche product, but it kind of starts or continues our discussion with the FDA around what this clinical trial design look like and for all of our programs. So that's really, I think, the more important thing to think about with the ELAP.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. Obviously, touch on those 2 acquisitions, discussed about investment in the facilities for the xeno pipeline. Potentially, we'll have a lot of cash if you mean your goals over the next several years. I guess how does BD factor into that is BD a priority for the pipeline? And what would you be interested in?

**James C. Edgemon** - United Therapeutics Corporation - CFO & Treasurer

Yes. So thank you. So just to remind maybe the audience, we do have a capital allocation kind of waterfall. And in order the priorities for us continue to be research and development, which means we're investing in ourselves, both in clinical trials as well as facilities. And the second capital allocation

MARCH 05, 2024 / 5:50PM, UTHR.OQ - United Therapeutics Corp at TD Cowen Health Care Conference

priority is business development. And there, we do dedicate time, dedicate resources to look at opportunities that we can bring into the organization to provide the highest and best use of capital. We try and be very thoughtful. And we look at organizations that are synergistic to the strengths of UT and the unitarians for manufacturing to sales, the clinical trials and even as Michael just discussed, show in manufactured organs.

So it is something that we continue to look at. We just want to be very thoughtful about bringing something in and making sure we have the right resources to advance that forward and the areas could be cardiovascular, again, things where we have strength and knowledge of rare lung disease. Again, as Michael talked about, getting into the organ manufacturing space to supplement and bring in new ideas and technologies that advance that overall program forward.

**Joseph John-Charles Thome** - TD Cowen, Research Division - MD & Senior Research Analyst

Perfect. Excellent. And with that, we are out of time. So thank you all for joining us.

**Michael I. Benkowitz** - United Therapeutics Corporation - President & COO

Thank you.

**James C. Edgemon** - United Therapeutics Corporation - CFO & Treasurer

Thank you.

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For Immediate Release

## United Therapeutics Corporation Announces \$1 Billion Accelerated Share Repurchase Program

*Repurchase reflects the strength of United Therapeutics' balance sheet and confidence in its near-term prospects*

SILVER SPRING, Md. and RESEARCH TRIANGLE PARK, N.C., March 25, 2024: United Therapeutics Corporation (Nasdaq: **UTHR**), a public benefit corporation, today announced that its Board of Directors has authorized the company to purchase up to \$1 billion of United Therapeutics' common stock. This program builds on United Therapeutics' planned \$400 million paydown of its revolving credit facility in 2024, of which \$100 million was paid down during the first quarter of 2024.

To enact the program, United Therapeutics today will enter into an Accelerated Share Repurchase (**ASR**) agreement with Citibank, N.A. (**Citi**) to repurchase \$1 billion of the company's common stock.

"We're in a unique position with a solid, growing, and profitable cash-generating business along with the potential to revolutionize the way end-stage organ disease is treated through an unlimited supply of tolerable, transplantable organs," said **Martine Rothblatt, Ph.D.**, Chairperson and Chief Executive Officer of United Therapeutics. "Having learned a great deal through the construction and commissioning of the world's first clinical-scale designated pathogen-free facility to support our xenotransplantation efforts, we are confident in our ability to fund future facilities while balancing prudent capital allocation for all of our stakeholders. The current valuation of United Therapeutics' stock makes repurchases of UTHR shares a solid investment and represents a chance to enhance long-term shareholder value."

Under the terms of the ASR agreement, on March 27, 2024, United Therapeutics will make an aggregate upfront payment of \$1 billion to Citi and will receive an initial delivery of shares representing approximately 80% of the total shares that would be repurchased under the ASR agreement measured based on the closing stock price of UTHR's common stock on March 25, 2024. The final number of shares that United Therapeutics will ultimately repurchase pursuant to the ASR agreement will be based on the average of the daily volume-weighted average price per share of United Therapeutics' common stock during the term of the ASR, less a discount and subject to adjustments pursuant to the terms and conditions of the ASR agreement. At final settlement of the ASR agreement, United Therapeutics may be entitled to receive additional shares of United Therapeutics' common stock, or, under certain limited circumstances, be required to make cash payment to Citi or, if United Therapeutics elects, deliver shares to Citi. The final settlement of the ASR is expected to be completed in the second quarter of 2024 with respect to \$300 million of the ASR and in the third quarter of 2024 with respect to \$700 million of the ASR. As of February 14, 2024, United Therapeutics had approximately 47.1 million shares outstanding.

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall it constitute an offer, solicitation, or sale in any jurisdiction in which such offer, solicitation, or sale is unlawful.

## **United Therapeutics: Enabling Inspiration**

At United Therapeutics, our vision and mission are one. We use our enthusiasm, creativity, and persistence to innovate for the unmet medical needs of our patients and to benefit our other stakeholders. We are bold and unconventional. We have fun; we do good. We are the first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC). Our public benefit purpose is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs.

You can learn more about what it means to be a PBC here: [unither.com/pbc](https://unither.com/pbc).

## **Forward-Looking Statements**

Statements included in this press release that are not historical in nature are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, among others, statements related to our confidence in our near-term prospects; the amount of our planned paydown of our revolving credit facility; the growth of our business; our potential to revolutionize the way end-stage organ disease is treated; our ability to fund future facilities; the benefits of the share repurchase to shareholders; our plan to enter into an ASR agreement; the number of shares to be repurchased under the ASR agreement; the timing and manner of the final settlement under the ASR agreement; and our goals of innovating for the unmet medical needs of our patients and to benefit our other stakeholders, furthering our public benefit purpose of developing novel pharmaceutical therapies and technologies that expand the availability of transplantable organs. These forward-looking statements are subject to certain risks and uncertainties, such as those described in our periodic reports filed with the Securities and Exchange Commission, that could cause actual results to differ materially from anticipated results. Consequently, such forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. We claim the protection of the safe harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We are providing this information as of March 25, 2024, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events, or any other reason.

### **For Further Information Contact:**

Dewey Steadman at (202) 919-4097  
<https://ir.unither.com/contact-ir/>

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS )  
CORPORATION, )  
 )  
Plaintiff, )  
 )  
v. ) C.A. No. 20-755 (RGA)  
 )  
LIQUIDIA TECHNOLOGIES, INC., )  
 )  
Defendant. )

**PLAINTIFF'S LETTER BRIEF IN SUPPORT OF MOTION TO STAY**

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April 1, 2024



Dear Judge Andrews:

United Therapeutics Corporation (“UTC”) respectfully moves this Court to stay its Order (D.I. 479) and Amended Final Judgment (D.I. 480) (collectively, “Rule 60(b) Decision”) granting Liquidia Technologies, Inc.’s (“Liquidia”) Motion for Post Judgment Relief Pursuant to Federal Rule of Civil Procedure 60(b) pending UTC’s forthcoming appeal to the Federal Circuit.

This Court’s Rule 60(b) Decision “vacate[d] the portion of the final judgment that blocks the final approval of Liquidia’s NDA.” D.I. 479. A stay of that decision pending appeal is necessary because now, no court order enjoins Liquidia’s imminent launch of its proposed Yutrepia™ product and a launch of Yutrepia would irreparably harm UTC while its request for review by the Supreme Court is forthcoming. By contrast, a stay will preserve the status quo and allow the Federal Circuit to address the issue of first impression that UTC’s appeal raises regarding when an agency decision becomes binding on a district court final judgment in a closed case, *before* the market is prematurely flooded with Liquidia’s follow-on product. As shown below, such relief is warranted under the circumstances.

## **I. This Court Should Stay Its Order and Amended Final Judgment Pending Appeal**

Courts consider four factors in deciding whether to grant a stay pending appeal: “(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies.” *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990) (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987); *In re Revel AC, Inc.*, 802 F.3d 558, 565 (3d Cir. 2015) (applying the same standard). “There is substantial overlap between these and the factors governing preliminary injunctions . . . because similar concerns arise whenever a court order may allow or disallow anticipated action before the legality of that action has been conclusively determined.” *Nken v. Holder*, 556 U.S. 418, 434 (2009).

In considering whether to grant a stay pending appeal, this Court uses a “sliding scale approach” in which “the four factors [are] effectively [] merged” and the court “assesses [the] movant’s chances for success on appeal and weighs the equities as they affect the parties and the public.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537 (D. Del. 2005) (quoting *Standard Havens*, 897 F.2d at 513). Thus, “[w]hen harm to applicant is great enough, a court will not require ‘a strong showing’ that applicant is ‘likely to succeed on the merits.’” *Standard Havens*, 897 F.2d at 513 (quoting *Hilton*, 481 U.S. at 776). Rather, “if the harm factors weigh heavily in movant’s favor, it need only demonstrate a substantial case on the merits.” *Jacobson v. Lee*, 1 F.3d 1251 (Fed. Cir. 1993).

### **A. UTC Can Win on the Merits or, at Least, Present a Substantial Case, and Will Suffer Significant Irreparable Harm Absent a Stay**

UTC’s appeal is likely to succeed on the merits or, at least, present a substantial case, because the Court’s reliance on *XY, LLC v. Trans Ova Genetics*, 890 F.3d 1282 (Fed. Cir. 2018) was misplaced. As a preliminary matter, UTC does not take issue with Your Honor’s recognition that under Federal Circuit precedent, a court of appeals’ “affirmance renders final a judgment on the invalidity of the [asserted claims], and has an *immediate* preclusive effect on any pending or co-pending actions involving the patent.” D.I. 479 (quoting *XY, LLC*, 890 F.3d at 1294) (alteration in original). However, the reach of *XY* explicitly extends only so far as to *pending or co-pending*

Hon. Richard G. Andrews  
Page 2

April 1, 2024

actions. Relevant here, *XY* does not address whether an affirmance of a lower tribunal’s judgment of invalidity has a preclusive effect on *terminated* cases involving the same patent. Indeed, when an agency decision becomes binding on a district court final judgment in a *closed* case presents an issue of first impression for the Federal Circuit, on which UTC is likely to prevail.

Put plainly, this case was terminated and closed once Liquidia’s petition for a writ of certiorari was denied. The ’793 IPR is not yet terminated or closed until the Supreme Court decides UTC’s forthcoming petition for a writ of certiorari, and if granted, until the Supreme Court’s merits review is complete. The ’793 IPR determination should not upend the terminated and closed case, let alone before UTC has fully exhausted its appellate rights with respect to the ’793 IPR.

UTC would suffer irreversible and irreparable harm if the Supreme Court grants review after this Court unwinds the portion of the Final Judgment (D.I. 436) that blocks the final approval of Liquidia’s NDA. In particular, even if Yutrepia were ultimately withdrawn from the market after launch, the injury to UTC would nevertheless be irreparable “because market share is so difficult to recover.” *Fresenius Kabi USA, LLC v. Fera Pharms., LLC*, 2016 WL 5348866, at \*13 (D.N.J. Sept. 23, 2016). Liquidia’s premature access to the market for dry powder formulations of treprostinil would also erode UTC’s first-mover advantage and facilitate Liquidia’s ability to re-launch when the ’793 patent expires, imposing a severe harm on UTC that would be difficult to quantify. *Cf. United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 23-975, D.I. 29 ¶ 91.

Moreover, the severity of irreparable harm to UTC absent a stay tips the scales in favor of granting a stay. *Standard Havens*, 897 F.2d at 513. With this Court’s decision to grant Liquidia’s 60(b) motion, no court order enjoins Liquidia from launching Yutrepia, and indeed, Liquidia has announced that it will launch Yutrepia immediately upon FDA approval. Ex. A (Feb. 26, 2024 Email Thread); Ex. B (Liquidia Press Release, Mar. 13, 2024). If Liquidia is allowed to prematurely launch its competing product, UTC will be irreparably harmed in several ways, including lost market share, price erosion, and reputational harm, that are irreversible, impossible to quantify with precision, and that Liquidia cannot rectify. For example, a Yutrepia launch would result in demands from payors for additional rebates or discounts, causing lasting price erosion to UTC’s Tyvaso products even if Yutrepia were removed from the market. *See* No. 23-cv-975, D.I. 29 ¶¶ 16, 18, 63–76; D.I. 26 at 16–17. Additionally, Yutrepia would directly compete with UTC’s Tyvaso products, eroding UTC’s sales and market share and making it “impossible to restore [UTC]’s . . . exclusive position by an award of damages and a permanent injunction.” *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996); No. 23-975, D.I. 29 ¶¶ 17, 86–95, D.I. 26 at 17–18. Even if some of the harm to UTC from Liquidia’s Yutrepia launch is quantifiable, the harm to UTC is irreparable because Liquidia is likely unable to compensate UTC— notwithstanding Liquidia’s most recent funding efforts. A stay of the Rule 60(b) Decision pending appeal is the only remedy to protect UTC from this harm.

Unless and until the claims of the ’793 patent are canceled following exhaustion of all of UTC’s appellate rights, Liquidia should not have been excused from this Court’s judgment. The Federal Circuit has already explained in this very case that “the Board’s final written decision does not cancel claims; the claims are canceled when the Director issues a certificate confirming unpatentability, which occurs only after ‘the time for appeal has expired or any appeal has terminated.’” *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1372 (Fed. Cir. 2023) (quoting 35 U.S.C. § 318). Here, while the Federal Circuit’s mandate in the IPR appeal has issued, the USPTO has not issued a certificate cancelling the claims of the ’793 patent. Only then

Hon. Richard G. Andrews  
Page 3

April 1, 2024

does a patent “no longer confer[] any rights that support an injunction.” *ePlus, Inc. v. Lawson Software, Inc.*, 789 F.3d 1349, 1356 (Fed. Cir. 2015).

At a minimum, the Court should grant a temporary stay to allow time for the Federal Circuit to consider whether to enter a stay of the Rule 60(b) Decision pending merits review of this issue.

### **B. The Balance of Equities Favors Granting a Stay**

Liquidia will suffer minimal, if any, harm as a result of a stay pending appeal. Liquidia’s position will not change if the stay is granted, as it has not launched yet and a stay would merely maintain the status quo. Any harm to Liquidia would last only for the time it takes to resolve UTC’s appeal. In other words, Liquidia will be in the *same exact position* as it is today if a stay pending appeal is granted. *Impax Lab’ys, Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002) (finding minimal hardship where defendant will be “in the same position as it was in before the injunction was granted”). Further, a stay would not threaten Liquidia’s ability to continue operating; Liquidia has recently touted to the public that it is “very well capitalized” and that, in light of “the \$126 million that [it] has raised,” it has “never been in a stronger position.” No. 23-975, D.I. 27 Ex. 3 at 7–8, 12–13 (“[W]e have the proper amount of fuel to really fire it on all cylinders on all things we’re trying to achieve.”).

In any event, any harm to Liquidia for having to wait to launch on the PAH indication is self-inflicted, and therefore *de minimis*. Liquidia cannot raise a cognizable harm that it will suffer as a result of the stay because any delay-related harm that Liquidia will suffer is a result of its own decision to litigate the alleged obviousness of the ’793 patent in an IPR instead of before this Court. *Pappan Enters., Inc. v. Hardees Food Sys., Inc.*, 143 F.3d 800, 806 (3d Cir. 1998) (tipping scale in favor of proponent because any harm to the party opposing relief was “self-inflicted”).

Moreover, the public interest favors resolving UTC’s appeal of the Rule 60(b) Decision before the market is prematurely flooded with Liquidia’s follow-on product. Courts have recognized that “[t]he fundamental purpose of a stay pending appeal is the preservation of the status quo.” *See, e.g., In re Zohar III, Corp.*, 2019 WL 6910285, at \*8 (D. Del. Dec. 19, 2019). Likewise, granting UTC’s request for a stay of the Rule 60(b) Decision pending appeal serves the public interest by fulfilling the precise “fundamental purpose” for which the stay mechanism was intended. *See id.*; *see also, e.g., Howard Johnson Int’l, Inc. v. Univ. Hosp., LLC*, 2018 WL 2095595, at \*3 (D.N.J. May 7, 2018) (“Defendant is correct that there is an interest in maintaining the status quo while an appeal is pending”). Recognizing this fundamental purpose, this Court has imposed temporary stays pending appeal to allow appellate review of adverse Patent Office actions in the past. *E.g., Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 2008 WL 5351038, at \*1 (D. Del. Dec. 22, 2008). As explained above, if Your Honor does not grant the requested stay, the impending launch of Liquidia’s Yutrepia product will irreversibly destroy the status quo, depleting UTC’s assets while it is simultaneously left to expend additional resources to prosecute the instant issue of first impression in the Federal Circuit. Once Liquidia’s figurative barn-door has been opened, it can never be reclosed.

## **II. Conclusion**

For these reasons, UTC respectfully requests that this Court stay the Rule 60(b) Decision pending UTC’s appeal to the Federal Circuit. In the alternative, at a minimum, the Court should stay the Rule 60(b) Decision for 14 days to allow UTC to petition the Federal Circuit for a permanent stay pending appeal.

Hon. Richard G. Andrews  
Page 4

April 1, 2024

Respectfully submitted,



Michael J. Flynn (#5333)  
*Counsel for Plaintiff*  
*United Therapeutics Corporation*

cc: Clerk of the Court  
All counsel of record

# EXHIBIT A

---

**From:** Sukduang, Sanya <ssukduang@cooley.com>  
**Sent:** Monday, February 26, 2024 6:05 PM  
**To:** Jackson, William C; Flynn, Michael J.  
**Cc:** Davies, Jonathan; kkeller@shawkeller.com; Nate Hoeschen; Dcarsten@mwe.com; Cheng, Katherine; Adykhuis@mwe.com; aburrowbridge@mwe.com; Lobel, Louis; Romeo, Eric; Mhkim@mwe.com; z/Liquidia v UTC 308970-201  
**Subject:** [EXT] RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

William,

We agree a TRO is a waste of time, resources and not well supported. This is an issue completely of UTC's own making. UTC knew from the date of FDA approval of PH-ILD that its regulatory exclusivity would expire at the end of March 2024. UTC filed suit in September 2023 asserting the 793 patent based on Liquidia's addition of PH-ILD and knew Liquidia intended to launch upon FDA approval. Yet, UTC did not file a PI at that time. UTC amended its complaint on November 30, 2023 to add the '327 patent, knowing Liquidia would launch and knowing the date of expiry of regulatory exclusivity—no PI was filed. On December 6, 2023, upon a direct request from you, Liquidia expressly and unequivocally informed UTC that it will launch upon final FDA approval. UTC did not file a PI then. Thus, the immediacy and harm UTC alleges is a fallacy and nonetheless, caused by UTC. These facts are not in dispute.

Liquidia will not agree to delay launching until resolution of UTC's PI motion.

Thanks  
Sanya

---

**From:** Jackson, William C <WJackson@goodwinlaw.com>  
**Sent:** Monday, February 26, 2024 5:02 PM  
**To:** Sukduang, Sanya <ssukduang@cooley.com>; Flynn, Michael J. <mflynn@morrisnichols.com>  
**Cc:** Davies, Jonathan <jdavies@cooley.com>; kkeller@shawkeller.com; Nate Hoeschen <nhoeschen@shawkeller.com>; Dcarsten@mwe.com; Cheng, Katherine <KatherineCheng@goodwinlaw.com>; Adykhuis@mwe.com; aburrowbridge@mwe.com; Lobel, Louis <LLobel@goodwinlaw.com>; Romeo, Eric <ERomeo@goodwinlaw.com>; Mhkim@mwe.com; z/Liquidia v UTC 308970-201 <zLiquidiaUTC308970201@cooley.com>  
**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

[External]

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Sanya:

It has occurred to us that the briefing schedule that you requested means that UTC's regulatory exclusivity on ILD will expire before the briefing on the PI is complete. It is possible that the FDA may act in the interim. Will Liquidia agree not to launch before Judge Andrews rules on the preliminary injunction motion? If not, we will be forced to file a request for a temporary restraining order, which we think is a waste of time and resources.

Let us know.

William C Jackson



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**From:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Sent:** Monday, February 26, 2024 9:11 AM  
**To:** Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>; Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
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**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

\*\*\*EXTERNAL\*\*\*

William,

We disagree with many of UTC's positions below, but the facts concerning UTC's prior notice of Liquidia's intent to launch have been confirmed in your email below. We see no need for a further meet and confer.

Thanks  
Sanya

---

**From:** Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>  
**Sent:** Saturday, February 24, 2024 3:54 PM  
**To:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>; Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
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**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

[External]

Sanya:

As I am sure you expected, there are a number of statements and characterizations in your email below with which we disagree. For example:

1. **Question 1:** Liquidia currently is enjoined from launching based on the judgment from the prior D. Del. case. But Liquidia has a pending Rule 60 motion for relief from that judgment. The Court could rule on that motion at any time. Should that motion be granted, there would be no impediment to Liquidia launching its LIQ861 product. Should the Court grant the motion and Liquidia launch its product for ILD, UTC would be irreparably harmed. **UTC proposed that, in order to avoid having to brief a preliminary injunction now, the parties agree that, if the Court were to grant the pending Rule 60 motion in the prior case, UTC would have 5 days to file a preliminary injunction motion and Liquidia would not launch its product for the ILD indication**



during the pendency of those preliminary injunction proceedings. Such an agreement would obviate the need for a preliminary injunction motion now (and potentially at all). Liquidia has now rejected that proposal.

2. **Question 2:** The APA action against the FDA asserts that the FDA violated its own “Bundling Rule” and allowed Liquidia to seek to add the ILD indication as an amendment rather than a separate NDA. Those proceedings, alleging a violation of the Administrative Procedures Act, are entirely distinct from these proceedings in which UTC alleges that Liquidia is infringing its ’327 patent. Nor is Liquidia even a party to those proceedings.
3. **Questions 3-4:** The parties did meet and confer in December about entirely different issues in this case. During that conversation, the possibility of a preliminary injunction was referenced. But I believe the focus of the meet and confer in December was the schedule for Liquidia answering or otherwise responding to the Amended Complaint that UTC had filed.
4. **Question 5:** As I indicated, in the NC case UTC has consistently sought to accommodate both parties’ reasonable scheduling requests. By contrast, after providing an expert report in the NC case, Liquidia stated that its expert was available for deposition on a single day in the entire expert discovery period, including weekends, and refused to agree to extend the expert discovery period to accommodate the schedules of those involved. It was for that reason that we were forced to seek the NC court’s assistance. We are corresponding with you and NC counsel with respect to the proposal to adjust the NC expert deposition calendar.
5. **Questions 6-8:** We agree with your summaries below and look forward to hearing from you with respect to the deposition dates for Dr. Nathan and Mr. Selck.

We are available should Liquidia believe that further meet and confer efforts would be productive. Thanks.

William C Jackson



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**From:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>  
**Sent:** Friday, February 23, 2024 4:47 PM  
**To:** Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>  
**Cc:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; Jackson, William C <[WJackson@goodwinlaw.com](mailto:WJackson@goodwinlaw.com)>; [Dcarsten@mwe.com](mailto:Dcarsten@mwe.com); Cheng, Katherine <[KatherineCheng@goodwinlaw.com](mailto:KatherineCheng@goodwinlaw.com)>; [Adykhuism@mwe.com](mailto:Adykhuism@mwe.com); [aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com); Lobel, Louis <[LLobel@goodwinlaw.com](mailto:LLobel@goodwinlaw.com)>; Romeo, Eric <[ERomeo@goodwinlaw.com](mailto:ERomeo@goodwinlaw.com)>; [Mhkim@mwe.com](mailto:Mhkim@mwe.com); z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>  
**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

\*\*\*EXTERNAL\*\*\*

Counsel,

I write to summarize the parties’ meet and confer concerning UTC’s anticipated PI motion, which was attended by Sanya Sukduang, Karen Keller, and Lauren Strosnick for Liquidia and William Jackson, Doug Carsten, and Michael Flynn for UTC.

The parties addressed the questions presented below.



Question 1, UTC recognized that it was seeking an injunction despite already having an injunction preventing the launch of Yutrepia. UTC offered to hold-back its proposed PI until after the Court decides Liquidia's Rule 60 Motion if Liquidia agreed to (a) grant UTC 5 days to decide to file a PI; and (b) if filed, not launch until the PI was resolved. **We presented this offer to Liquidia, but Liquidia cannot agree to this proposal.**

Question 2, UTC asserted that the APA action against the FDA seeks different relief than the proposed PI. Liquidia disagreed, indicating that the PI seeks to enjoin Liquidia from launching in PH-ILD and UTC's FDA action seeks to compel the FDA to revoke any approval of Yutrepia for PH-ILD and force Liquidia to refile. In short, both seek to enjoin Liquidia from launching Yutrepia in PH-ILD.

Questions 3-4, UTC asserted that it became aware of "recent" press release regarding Liquidia's anticipated launch and this "recent" notice was required to file a PI. UTC acknowledged, however, that the parties did conduct a meet and confer prior to December 25, 2023 (the exact date was December 6, 2023), where Liquidia provided notice, as expressly requested by UTC's counsel Mr. Jackson, that it would launch Yutrepia immediately upon FDA approval. UTC's counsel also agreed that during the December 6, 2023 meet and confer, Mr. Flynn suggested the parties contact the Court to address a PI briefing schedule.

Question 5, Liquidia asked if UTC would be amenable to postpone the UTC witness expert depositions in the NC trade secret case, to which UTC said it was. **Liquidia will submit a proposal to NC counsel shortly.**

Question 6, UTC indicated it intends to file its PI motion on Monday or Tuesday of next week.

Question 7, UTC has identified 2 experts (Dr. Nelson and Mr. Selck). Dr. Nelson is available for deposition on March 10 and Mr. Selck sometime thereafter. Liquidia is looking to see if those dates work.

Question 8, Liquidia requests an extension, until **April 5, 2024** to file its opposition, which UTC indicated it would consent to. UTC's requested two-weeks after Liquidia files its opposition to file its reply, to which Liquidia consents.

Thanks  
Sanya

---

**From:** Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>

**Sent:** Thursday, February 22, 2024 12:50 PM

**To:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>

**Cc:** Davies, Jonathan <[jdavies@cooley.com](mailto:jdavies@cooley.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); Nate Hoeschen <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; William Jackson (Goodwin) <[wjackson@goodwinlaw.com](mailto:wjackson@goodwinlaw.com)>; Douglas H. Carsten - McDermott Will & Emery LLP ([dcarsten@mwe.com](mailto:dcarsten@mwe.com)) <[dcarsten@mwe.com](mailto:dcarsten@mwe.com)>; Cheng, Katherine <[KatherineCheng@goodwinlaw.com](mailto:KatherineCheng@goodwinlaw.com)>; Art Dykhuis - McDermott Will & Emery LLP ([adykhuis@mwe.com](mailto:adykhuis@mwe.com)) <[adykhuis@mwe.com](mailto:adykhuis@mwe.com)>; Burrowbridge, Adam W. (MWE) <[aburrowbridge@mwe.com](mailto:aburrowbridge@mwe.com)>; Lobel, Louis <[LLobel@goodwinlaw.com](mailto:LLobel@goodwinlaw.com)>; Romeo, Eric <[ERomeo@goodwinlaw.com](mailto:ERomeo@goodwinlaw.com)>; [Mhkim@mwe.com](mailto:Mhkim@mwe.com); z/Liquidia v UTC 308970-201 <[zLiquidiaUTC308970201@cooley.com](mailto:zLiquidiaUTC308970201@cooley.com)>

**Subject:** RE: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

**[External]**

---

Sanya,

We are available at 12:00 ET on Friday for a call and look forward to discussing your questions below.

Click to join meeting: <https://meet.loopup.com/45xeX0IXC8>

**Or dial in:**

US Toll Free: 1 877 304 9269

Passcode: **3023519661#**

Mobile Quick Join: <tel://+18773049269,,3023519661#>

---

**MICHAEL J. FLYNN**

Partner | Morris, Nichols, Arsht & Tunnell LLP

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---

**From:** Sukduang, Sanya <[ssukduang@cooley.com](mailto:ssukduang@cooley.com)>

**Sent:** Wednesday, February 21, 2024 9:51 PM

**To:** Flynn, Michael J. <[mflynn@morrisnichols.com](mailto:mflynn@morrisnichols.com)>

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McDermott Will & Emery LLP (<[adykhuis@mwe.com](mailto:adykhuis@mwe.com)> <[adykhuis@mwe.com](mailto:adykhuis@mwe.com)>; Burrowbridge, Adam W. (MWE)

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[Mhkim@mwe.com](mailto:Mhkim@mwe.com); z/Liquidia v UTC 308970-201 <[zLiquidiavUTC308970201@cooley.com](mailto:zLiquidiavUTC308970201@cooley.com)>

**Subject:** [EXT] Re: UTC/Liquidia (23-975) - Meet & Confer on Prelim. Inj. Motion

Michael

We aren't available tomorrow, but can be Friday except between 3:00-4:00 pm, contingent upon UTC's ability to respond to the issues below .

During the call, we expect UTC to specifically address the following, and failure to do so will be raised with the Court:

1. Why UTC believes a PI is needed in this action given UTC's position, articulated as recently as yesterday, that the Court's 793 injunction cannot be lifted until the 793 claims are cancelled by the Director;
2. Why a PI is needed given UTC's complaint against the FDA that Yutrepia should not be launched;
3. UTC's delay, until February 21, 2024, to address a PI given the parties' specific discussion with you and William Jackson of a PI request prior to December 25, 2023 and Liquidia's request to address any potential PI briefing such that UTC does not force Judge Andrews to act expeditiously;
4. Why, despite filing a complaint 3 months ago concerning the '327 patent, UTC has waited to file a PI;
5. Why a PI is warranted given UTC's request for a 30 day extension of time to answer Liquidia's counterclaims based on proceedings in an unrelated litigation in NC and why Liquidia is also not entitled to rely on the schedule in NC to support a non-conflicting schedule;
6. The specific date UTC intends to file its PI motion and any declarations it may file in support;
7. The dates any UTC declarant is available for a deposition; and
8. The briefing schedule UTC proposes.

This above list is non-limiting and Liquidia may raise additional issues based on UTC's responses.



\*\*\*\*\*

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litigation in the U.S. District Court for the District of Delaware, inter partes review proceedings conducted at the PTAB or other litigation instituted by United Therapeutics or others, including rehearings or appeals of decisions in any such proceedings, the issuance of patents by the USPTO and our ability to execute on our strategic or financial initiatives, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. The favorable decisions of courts or other tribunals are not determinative of the outcome of the appeals or rehearings of the decisions. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks discussed in our filings with the SEC, as well as a number of uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and our industry has inherent risks. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the future events discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Nothing in this press release should be regarded as a representation by any person that these goals will be achieved, and we undertake no duty to update our goals or to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.

## Company Contacts

### Investors:

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Chief Business Officer  
919.328.4400  
[jason.adair@liquidia.com](mailto:jason.adair@liquidia.com)

### Media Inquiries:

[media@liquidia.com](mailto:media@liquidia.com)

## Liquidia Corporation Select Balance Sheet Data

	December 31, 2023	December 31, 2022
Cash and cash equivalents	\$ 83,679	\$ 93,283
Total assets	\$ 118,332	\$ 129,198
Total liabilities	\$ 71,039	\$ 38,776
Accumulated deficit	\$ (429,098)	\$ (350,596)
Total stockholders' equity	\$ 47,293	\$ 90,422

## Liquidia Corporation Consolidated Statements of Operations and Comprehensive Loss

	Year Ended December 31, 2023	Year Ended December 31, 2022
Revenue	\$ 17,488	\$ 15,935
Costs and expenses:		
Cost of revenue	2,888	2,859
Research and development	43,242	19,435
General and administrative	44,742	32,411
Total costs and expenses	90,872	54,705
Loss from operations	(73,384)	(38,770)
Other income (expense):		
Interest income	3,466	1,090
Interest expense	(6,273)	(2,338)
Loss on extinguishment of debt	(2,311)	(997)
Total other income (expense), net	(5,118)	(2,245)
Net loss and comprehensive loss	\$ (78,502)	\$ (41,015)
Net loss per common share, basic and diluted	\$ (1.21)	\$ (0.67)
Weighted average common shares outstanding, basic and diluted	64,993,476	60,958,862







# EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)	
CORPORATION,	)	
	)	
Plaintiff	)	
	)	C.A. No. 23-975 (RGA)
v.	)	
	)	
LIQUIDIA TECHNOLOGIES, INC.,	)	
	)	
Defendant.	)	

**STIPULATION AND [PROPOSED] ORDER  
OF PARTIAL DISMISSAL WITHOUT PREJUDICE**

WHEREAS, on November 30, 2023, Plaintiff United Therapeutics Corporation (“UTC”) filed its First Amended complaint in this action (D.I. 8), alleging that defendant Liquidia Technologies, Inc. (“Liquidia”) has infringed U.S. Patent No. 10,716,793 (“the ’793 patent”) and U.S. Patent No. 11,826,327 (“the ’327 patent”) by seeking FDA approval to engage in the commercial manufacture, use, or sale of Liquidia’s proposed YUTREPIA® (treprostinil) drug product before expiration of the ’793 and ’327 patents;

WHEREAS, on December 20, 2023, the Federal Circuit issued an opinion (D.I. 14-1, “Federal Circuit Decision”), in which it affirmed a Final Written Decision of the United States Patent Trial and Appeal Board determining that the asserted claims of the ’793 patent are invalid as obvious;

WHEREAS, UTC intends to move for panel rehearing and/or rehearing *en banc* of the Federal Circuit Decision;

WHEREAS, UTC reserves the right to file a petition for certiorari with the U.S. Supreme Court should its petitions for rehearing be denied;

WHEREAS, the United States Patent and Trademark Office (“USPTO”) has not yet issued

a Certificate of Cancellation for asserted claims of the '793 patent; and

WHEREAS, on January 8, 2024, Liquidia moved this Court (D.I. 13) to dismiss Counts I and II of UTC's First Amended Complaint (D.I. 8), which allege infringement of the '793 patent.

NOW, THEREFORE, IT IS HEREBY STIPULATED AND AGREED, by and between all parties, through their respective undersigned counsel, subject to the approval of the Court:

1. Pursuant to Fed. R. Civ. P. 41(a), Counts I and II of UTC's First Amended Complaint (D.I. 8) are dismissed *without* prejudice, with each party to bear its own costs, expenses, and attorneys' fees.
2. Liquidia's Motion to Dismiss (D.I. 13) is denied as moot.
3. UTC may amend its Complaint in this action should the Federal Circuit Decision be vacated or reversed.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Michael J. Flynn*

---

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*/s/ Nathan R. Hoeschen*

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January 22, 2024

**IT IS SO ORDERED**, this 22 day of January, 2024.

/s/ Richard G. Andrews  
\_\_\_\_\_  
UNITED STATES DISTRICT JUDGE

# EXHIBIT 2

**CONFIDENTIAL MATERIAL OMITTED**

### United Therapeutics Tyvaso Forecast (2023-2035)

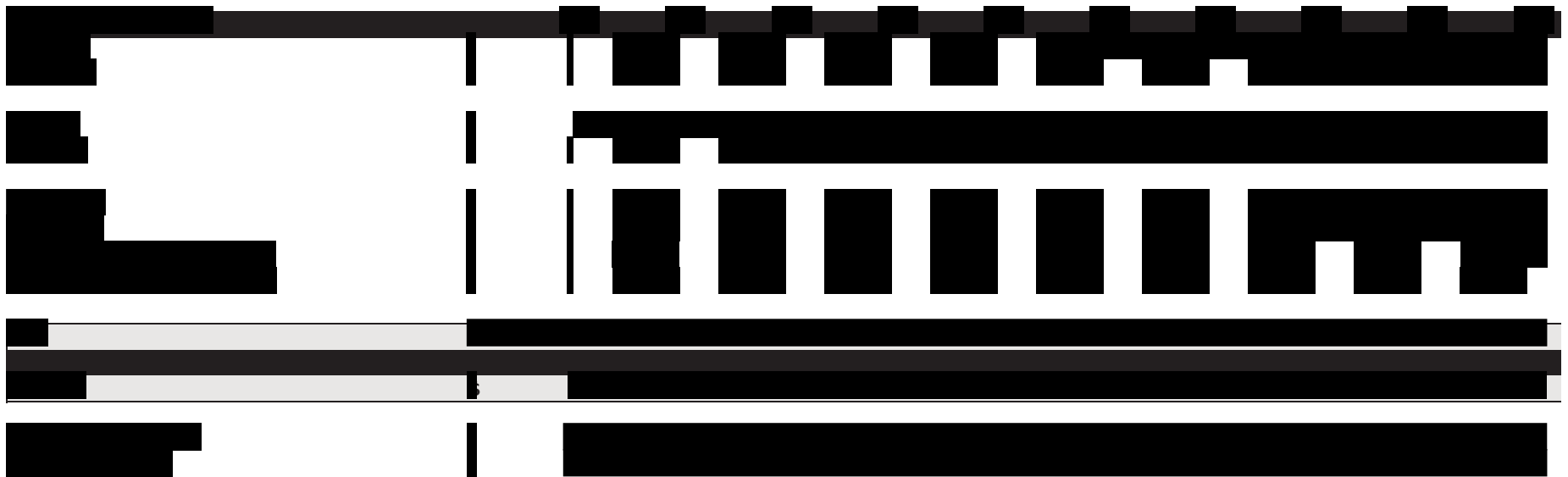
**CONFIDENTIAL MATERIAL OMITTED**

### United Therapeutics Tyvaso Forecast (2023-2035)

Category	Item	Value
Section 1	Item 1	100
	Item 2	200
	Item 3	300
	Item 4	400
	Item 5	500
	Item 6	600
	Item 7	700
	Item 8	800
	Item 9	900
	Item 10	1000
Section 2	Item 1	100
	Item 2	200
	Item 3	300
	Item 4	400
	Item 5	500
	Item 6	600
	Item 7	700
	Item 8	800
	Item 9	900
	Item 10	1000
Section 3	Item 1	100
	Item 2	200
	Item 3	300
	Item 4	400
	Item 5	500
	Item 6	600
	Item 7	700
	Item 8	800
	Item 9	900
	Item 10	1000



United Therapeutics Tyvaso Forecast (2023-2035)



Case: 24-1658 Document: 13 Page: 266 Filed: 04/26/2024

[illegible]

### United Therapeutics Tyvaso Forecast (2023-2035)

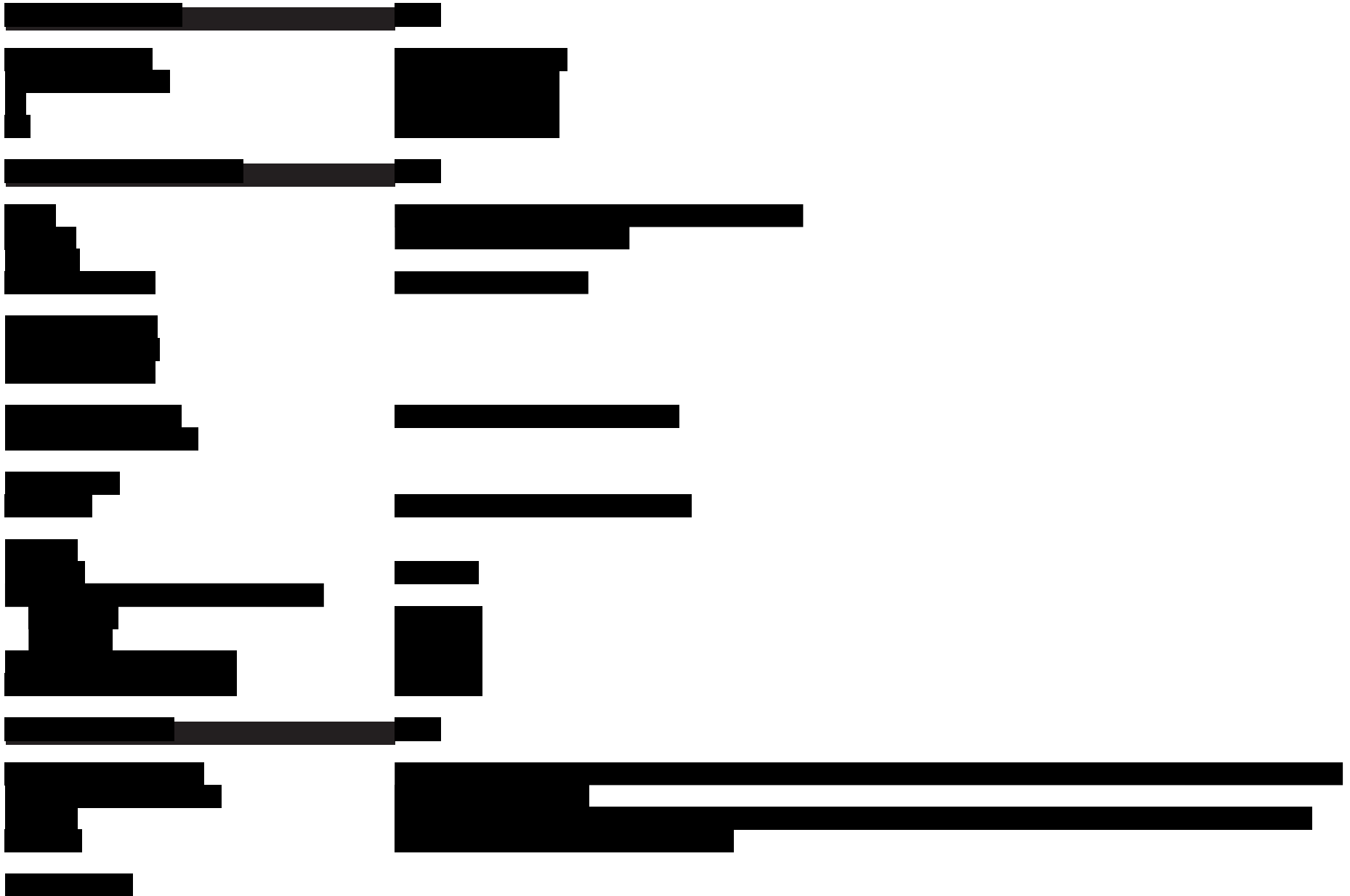
UTC\_24-1658\_Appeal\_000105

United Therapeutics Tyvaso Forecast (2023-2035)



CONFIDENTIAL MATERIAL OMITTED

United Therapeutics Tyvaso Forecast (2023-2035)



CONFIDENTIAL MATERIAL OMITTED

United Therapeutics Tyvaso Forecast (2023-2035)



Government	Percentage
Current government	85%
Previous government	15%

**IN THE UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

UNITED THERAPEUTICS CORPORATION,

Appellant,

v.

LIQUIDIA TECHNOLOGIES, INC.,

Appellee.

§  
§  
§  
§  
§  
§  
§  
§  
§  
§

No. 2024-1658

**DECLARATION OF DOUGLAS KIDDER**

**NON-CONFIDENTIAL VERSION**



Non-Confidential

**Table of Contents**

<b>1. Scope of Work .....</b>	<b>3</b>
<b>2. Qualifications .....</b>	<b>3</b>
<b>3. Summary of Opinions.....</b>	<b>4</b>
<b>4. Background .....</b>	<b>5</b>
4.1 UTC.....	5
4.2 Liquidia.....	8
4.3 '793 Patent.....	11
4.4 Request For a Stay .....	12
4.5 Timeline of Events .....	13
<b>5. Overview of the Selck Declaration .....</b>	<b>16</b>
<b>6. Evidence From UTC .....</b>	<b>16</b>
6.1 UTC Forecast.....	17
6.2 UTC Management's Statements.....	21
6.3 Stock Price Analysis.....	24
<b>7. Price Erosion .....</b>	<b>28</b>
<b>8. Lost Sales .....</b>	<b>30</b>
<b>9. Lost First Mover Advantage .....</b>	<b>31</b>
<b>10. Reduced Pipeline Investment .....</b>	<b>34</b>
<b>11. Reputational Harm.....</b>	<b>35</b>
<b>12. Irreparability .....</b>	<b>36</b>
<b>13. Balance of Equities .....</b>	<b>38</b>
<b>14. Signature Page .....</b>	<b>42</b>

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## 1. SCOPE OF WORK

1. I have been retained on behalf of Defendant Liquidia Technologies, Inc. (“Liquidia”) to review and comment on the declaration submitted by Frederic Selck dated April 17, 2024 (the “Selck Declaration”) on behalf of Plaintiff United Therapeutics Corporation (“UTC” or “UTHR”). I understand that UTC filed a motion with the United States Court of Appeals for the Federal Circuit seeking a stay of an amended judgment lifting an order that previously barred the U.S. Food and Drug Administration (FDA) from finally approving Liquidia’s Yutrepia product, which was previously alleged to infringe certain claims of UTC’s U.S. Patent No. 10,716,793 (the “’793 Patent”).<sup>1</sup>

2. The opinions contained in my report are based on the information and data available to me as of the date of serving this report. If new data or information becomes available, I expect to update or revise my opinions accordingly.

## 2. QUALIFICATIONS

3. My name is Douglas Kidder. I am a Managing Partner with OSKR, LLC, a firm that provides expert services primarily in the area of damages calculations generally with a particular focus on intellectual property and antitrust matters. I was also an adjunct professor at Golden Gate University, where I taught a graduate course on damages in the school of accounting. I am also a member of the Licensing Executives Society, a former Director of i-cap Partners – a venture capital fund investing in technology companies – and a former member of the Trade New Zealand advisory board – a group formed to review New Zealand-based startups for support entering the U.S. market.

4. I hold a B.A. in Mathematics and English with Honors from Amherst College (1983) and a Master of Science from the University of California at Berkeley (1986). While at Berkeley, I was a lecturer in the Computer Science department.

5. I have been performing business analyses and valuations for over thirty-five years, as a consultant, business owner, board member and manager. I have been retained by companies to render expert opinions in the context of litigation, to assist in licensing and evaluation of intellectual property that is not subject to litigation, and to develop and refine business strategies. I have published and spoken on business and valuation issues, mostly related to intellectual property. I have co-authored seven published articles relating to intellectual property damages. A copy of my resume is attached as Exhibit 1. A list of the documents considered in forming my opinions is attached as Exhibit 2.

---

<sup>1</sup> *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, Case No. 2024-1658 (Fed. Cir.), Doc. No. 11.

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6. I am being compensated at an hourly rate of \$750 per hour, plus reimbursement of expenses. I have been assisted in this matter by OSKR staff, working under my supervision and control. I have no financial interest in the outcome of this matter.

### 3. SUMMARY OF OPINIONS

7. Dr. Selck's opinions lack merit and are contradicted by evidence from UTC. Dr. Selck's opinions about price erosion and lost sales are directly refuted by UTC management's statements and internal forecasts. For example, UTC's Chairman and CEO, Martine Rothblatt stated publicly that:

I think our double-digit growth rate remains a solid forecast even with the possibility of new FDA approvals of sotatercept or Liquidia.<sup>2</sup>

A review of the evidence supports Dr. Rothblatt's statements. A UTC internal financial forecast [REDACTED]

8. Dr. Selck supports his opinions about price erosion and lost sales by a selective review of the evidence. His only support for price erosion is a single, undocumented conversation with a UTC employee.<sup>3</sup> As noted above, this undocumented conversation is contradicted by UTC management's public statements and its internal forecast. Dr. Selck's evidence for lost sales is an observation that the market will view the Tyvaso products and Yutrepia as alternatives.<sup>4</sup> However, Dr. Selck does not review the evidence that UTC believes that its share of patients taking Tyvaso for PAH and PH-ILD amounted to [REDACTED] – giving Yutrepia a chance to serve [REDACTED].<sup>5</sup>

9. Dr. Selck's additional opinions regarding indirect harms such as loss of first mover advantage, reputational harm, irreparability and the balance of equities fail because they all derive from his flawed opinions regarding lost sales and price erosion. There is no evidence in this case that any harm would be irreparable: damages will be calculable using standard patent damages methodologies and there is nothing to suggest that the quantum of damages will be so great that Liquidia will be unable to pay them. The

---

<sup>2</sup> LIQ\_24-1658\_Appeal\_0000114-124 at 116 [Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023]

<sup>3</sup> Selck Declaration, ¶¶58, 60.

<sup>4</sup> Selck Declaration, ¶80, § 4.1.

<sup>5</sup> [REDACTED]; UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101.

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balance of equities favors Liquidia. UTC has over \$4.9 billion in cash and a business that is generating an additional \$700 million in cash each year.<sup>6</sup>

#### 4. BACKGROUND

10. In the following sections I provide an overview of UTC, Liquidia and the dispute. The sections describing UTC and Liquidia also offer background into PAH, PH-ILD and therapies for treating these conditions.

##### 4.1 UTC

11. UTC describes itself as a public benefit corporation that sells a range of therapies:

We are the first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC). Our public benefit purpose is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs. At the same time, we seek to provide our shareholders with superior financial performance and our communities with earth-sensitive energy utilization.

We market and sell the following commercial therapies in the United States to treat PAH: Tyvaso DPI® (treprostinil) Inhalation Powder (Tyvaso DPI); Tyvaso® (treprostinil) Inhalation Solution (nebulized Tyvaso), which includes the Tyvaso Inhalation System; Remodulin® (treprostinil) Injection (Remodulin); Orenitram® (treprostinil) Extended-Release Tablets (Orenitram); and Adcirca® (tadalafil) Tablets (Adcirca). Tyvaso DPI and nebulized Tyvaso are also approved to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). In the United States, we market and sell an oncology product, Unituxin® (dinutuximab) Injection (Unituxin), which is approved for the treatment of high-risk neuroblastoma, and the Remunity® Pump for Remodulin (Remunity). Outside the United States, we derive revenues from sales of nebulized Tyvaso, Remodulin, and Unituxin.

We are actively advancing a pipeline of research and development projects that includes new indications and delivery devices for our existing products, as well as new products to treat PAH and other conditions. We are also focused on a variety of manufactured organ products with the goal of addressing the chronic shortage of transplantable organs for patients with end-stage organ diseases.<sup>7</sup>

12. In 2023 the majority of UTC's sales came from different formulations of Treprostinil with approximately half of its revenues came from sales of Tyvaso in the U.S.:

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<sup>6</sup> United Therapeutics Corporation Form 10-K for the year ending December 31, 2023 ("UTC 10-K, 2023"), p. 61.

<sup>7</sup> UTC 10-K, 2023, p. 3.

Non-Confidential

**Table 1: UTC Revenues by Product<sup>8</sup>**

13. UTC describes competition for its products as:

Many drug companies engage in research, development, and commercialization of products to treat cardiopulmonary diseases and cancer. For the treatment of PAH, we compete with many approved products in the United States and the rest of the world. In the U.S., these competitive therapies include oral ERAs (Letairis® (ambrisentan), Opsumit® (macitentan), Tracleer® (bosentan), generic bosentan, and generic ambrisentan); prostacyclin-class therapies (Flolan (intravenous epoprostenol), Uptravi® (oral selexipag), Veletri® (intravenous

	2023		
	U.S.	ROW	Total
Net product sales:			
Tyvaso DPI <sup>(1)</sup>	\$ 731.1	\$ –	\$ 731.1
Nebulized Tyvaso <sup>(1)</sup>	477.1	25.5	502.6
Total Tyvaso	1,208.2	25.5	1,233.7
Remodulin <sup>(2)</sup>	414.6	80.2	494.8
Orenitram	359.4	–	359.4
Unituxin	181.3	17.6	198.9
Adcirca	28.9	–	28.9
Other	9.8	2.0	11.8
Total revenues	\$2,202.2	\$ 125.3	\$2,327.5

epoprostenol), Ventavis® (inhaled epoprostenol), generic epoprostenol, and generic treprostinil injection); PDE-5 inhibitors (Revatio® (sildenafil), generic sildenafil, and generic tadalafil); and Adempas® (riociguat), an sGC stimulator that targets a similar vasodilatory pathway as PDE-5 inhibitors. These therapies are manufactured and marketed by large pharmaceutical companies such as Johnson & Johnson, Gilead Sciences, Inc., and Bayer Schering Pharma AG, as well as a variety of large generic drug manufacturers.

There are also a wide variety of investigational PAH therapies in development. Therapies in registration-phase studies, or which have completed registration-phase studies, include the following:

- Yutrepia a dry powder formulation of treprostinil developed by Liquidia, which is designed for pulmonary delivery using a disposable inhaler. In November 2021, Liquidia announced the FDA granted tentative approval for its NDA for Yutrepia to treat PAH, with final approval pending resolution of the regulatory stay triggered by the litigation described above under Patent and Other Property Rights, Strategic Licenses, and Market Exclusivity—Generic Competition and Challenges to our Intellectual Property Rights. In late 2020, Liquidia completed a business combination with RareGen, LLC, which markets a generic version of Remodulin manufactured by Sandoz. Liquidia has submitted an amendment to the Yutrepia NDA to include a PH-ILD

<sup>8</sup> UTC 10-K, 2023, p. F-33.

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indication. In September 2023, Liquidia announced that the FDA had accepted this amendment for review, and set a PDUFA target action date of January 24, 2024. On January 25, 2024, Liquidia announced that the FDA had not yet completed its review of the NDA and did not provide an updated timeline. The regulatory process concerning Liquidia's NDA is subject to the litigation described in Note 14—Litigation, to our consolidated financial statements.

- Sotatercept, an injected activin signaling inhibitor being developed by Acceleron Pharma, Inc. (Acceleron), which was acquired by Merck, to treat PAH through the TGF-beta signaling pathway. Merck announced positive top-line results of a phase 3, registration trial in PAH called STELLAR in October 2022, and submitted an NDA to the FDA with a PDUFA target action date of March 26, 2024. Acceleron indicated it may also study sotatercept in PH-ILD patients.
- Imatinib, a drug currently used to treat cancer under the trade name Gleevec®, is being developed separately for the treatment of PAH by three companies. Tenax Therapeutics, Inc. announced plans to initiate a phase 3 study of an oral formulation. Aerovate Therapeutics, Inc. is conducting a phase 2/3 clinical study of an inhaled, dry powder formulation of imatinib. Aerami Therapeutics Holdings, Inc. completed a phase 1 trial of an inhaled formulation of imatinib in 2023, and has announced plans for a phase 2 study in PAH and PH-ILD patients.
- MK-5475, an inhaled soluble guanylate cyclase stimulator being developed by Merck for PAH in a phase 2/3 trial and in a phase 2 trial for PH-COPD patients.
- L606, an inhaled, liposomal form of treprostinil being developed by Pharmosa Biopharm Inc. (Pharmosa) for PAH and PH-ILD, which completed a phase 1 study in healthy volunteers. In June 2023, Liquidia announced it had entered into an exclusive licensing agreement for development and commercialization of L606 in North America, and that the product is the subject of a phase 3 clinical trial in patients with PH-ILD, with the intent of obtaining approval for the treatment of both PAH and PH-ILD via the 505(b)(2) regulatory pathway, with nebulized Tyvaso as the reference listed drug.

Additional therapies being studied for PAH include Insmed Incorporated's TPIP (INS1009, an inhaled version of treprostinil) (phase 2); Keros Therapeutics' KER-012 (phase 2); Novartis' LTP001 (phase 2); Gossamer Bio, Inc.'s serralutinib (GB002) (phase 3); SoniVie's TIVUS™ (pivotal trial); Respira Therapeutics' vardenafil (RT234) (phase 2b); and Cerenio Scientific's valproic acid (CS1) (phase 2).

Oral non-prostacyclin therapies (such as PDE-5 inhibitors and ERAs) are commonly prescribed as first-line treatments for less severely ill PAH patients. As patients progress in their disease severity, additional advanced approved therapies, such as inhaled prostacyclin analogues (including Tyvaso DPI and nebulized Tyvaso) or infused prostacyclin analogues (including Remodulin) are then commonly added. Orenitram was the first approved oral prostacyclin-class therapy for PAH in the United States, and offers a more convenient alternative therapy to Remodulin, Tyvaso DPI, and nebulized Tyvaso. The use of available

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oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products. In addition, sotatercept presents a potential new way of treating PAH, and if approved, could provide added competition for our treprostinil-based therapies. A majority of patients enrolled in the STELLAR clinical trials of sotatercept were on background prostacyclin class therapies such as treprostinil. We believe sotatercept may offer a complementary treatment in combination with our treprostinil-based therapies, although some physicians could choose to prescribe sotatercept prior to initiating prostacyclin therapy.

...

Tyvaso DPI, nebulized Tyvaso, and our other treprostinil-based products may face competition from Liquidia if it obtains final FDA approval of Yutrepia, a dry powder inhaled version of treprostinil.

Aside from Tyvaso DPI and nebulized Tyvaso, there are currently no approved therapies to treat PH-ILD. Several PAH drug candidates are also being developed for PH-ILD (e.g., Yutrepia, L606, sotatercept, imatinib, and TPIP). Other companies are now developing, or may in the future develop, other therapies to treat PH-ILD. In addition, the use of antifibrotic therapies to treat underlying lung disease (such as the IPF therapies discussed below) could delay the onset of group 3 pulmonary hypertension.<sup>9</sup>

## 4.2 LIQUIDIA

14. Liquidia describes itself as a “biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension (‘PH’).”<sup>10</sup>

15. Liquidia currently generates revenue from sales of an injectable Treprostinil and is researching applications for its PRINT technology:

We currently generate revenue pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. (“Sandoz”) sharing profit derived from the sale of Sandoz’s substitutable generic treprostinil injection (“Treprostinil Injection”) in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension (“PAH”), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon potential approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.

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<sup>9</sup> UTC 10-K, 2023, pp. 19–20.

<sup>10</sup> Liquidia Corporation Form 10-K for the year ending December 31, 2022 (“Liquidia 10-K, 2022”), p. 3.

Non-Confidential

We conduct research, development, and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy, and performance of a wide range of therapies. Through development of our own products and research with third parties, we have experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.

Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of treprostinil designed with PRINT to improve the therapeutic profile of treprostinil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler (“DPI”) and by achieving higher dose levels than the labelled doses of current inhaled therapies. The United States Food and Drug Administration (“FDA”) tentatively approved our New Drug Application (“NDA”) for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity for the nebulized form of treprostinil in March 2024.<sup>11</sup>

16. Liquidia describes the patient population with PAH and PH-ILD and available therapies as:

PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death, with an estimated diagnosed, treated prevalence in the United States of approximately 30,000 to 45,000 patients. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression and improve quality of life.

PH-ILD is the second most prevalent form of Group 3 PH (precapillary PH due to lung disease). ILD is a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis (IPF), chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and sarcoidosis among others. Current estimates of diagnosed and undiagnosed prevalence of PH-ILD range between 30,000 to 70,000, depending on the growth on the underlying lung diseases. The prevalence of PH in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until recently.

...

The only inhaled prostacyclin analogs approved by the FDA are nebulized Ventavis® (iloprost), nebulized Tyvaso® (treprostinil), and Tyvaso DPI® (treprostinil), a dry powder inhaled formulation. With regard to PH-ILD, there is growing medical preference for inhaled therapies to avoid ventilation-perfusion mismatch resulting from systemic delivery of prostacyclins. In March 2021, the FDA approved Tyvaso® as the only treatment for PH-ILD, later

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<sup>11</sup> Liquidia 10-K, 2022, p. 3.



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adding Tyvaso DPI as a treatment option upon its approval by the FDA in May 2022.<sup>12</sup>

17. Liquidia believes that Yutrepia offers advantages relative to other therapies for PAH and PH-ILD:

We believe YUTREPIA can become the prostacyclin of first choice across the disease continuum in PAH and PH-ILD because of its convenience, low-resistance device and the ability to titrate to higher doses.

...

In clinical studies required for approval, YUTREPIA has proven to be safe, well-tolerated and effective regardless of a patient's previous exposure to treprostinil. Prostacyclin-naïve patients achieved comparable dosing to the transition patients within first two months of treatment. Patients on a stable dose of Tyvaso successfully transition to YUTREPIA while maintaining or improving clinical outcomes as measured by exploratory endpoints. The combination of data from both patient groups provide confidence that a physician may prescribe YUTREPIA across a continuum of PAH and PH-ILD patients.<sup>13</sup>

18. Liquidia identified the following competition for Yutrepia:

- Tyvaso ...
- Ventavis ...
- Tyvaso DPI ...
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmel. Insmel announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmel initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.
- L606 ...

There are also a variety of investigational PAH therapies in the later stages of development that target new or clinically-validated mechanism of actions (MOAs) that may benefit patients. The approval of some or any of these could change the treatment paradigm and impact the utilization of treprostinil products and the prostacyclin pathway at large. We believe that new MOAs may slow or reverse the disease progression of PAH having the net impact of increasing the diagnosed prevalent population by extending patient lives and increasing the potential addressable population for treprostinil-based therapies. For example, Merck & Co's injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the

<sup>12</sup> Liquidia 10-K, 2022, pp. 3–4.

<sup>13</sup> Liquidia 10-K, 2022, p. 5.

Non-Confidential

pulmonary vasculature and is being reviewed by the FDA for approval in 2023. If approved, we currently expect that the drug will be used as it was studied: on-top of dual and triple background therapy that included prostacyclin analogs.<sup>14</sup>

19. In 2023, Liquidia generated \$17.5 million in revenue and losses of \$78.5 million:

**Table 2: Liquidia Income Statement<sup>15</sup>**

	Year Ended December 31,	
	2023	2022
Revenue	\$ 17,488	\$ 15,935
Costs and expenses:		
Cost of revenue	2,888	2,859
Research and development	43,242	19,435
General and administrative	44,742	32,411
Total costs and expenses	90,872	54,705
Loss from operations	(73,384)	(38,770)
Other income (expense):		
Interest income	3,466	1,090
Interest expense	(6,273)	(2,338)
Loss on extinguishment of debt	(2,311)	(997)
Total other expense, net	(5,118)	(2,245)
Net loss and comprehensive loss	\$ (78,502)	\$ (41,015)

#### 4.3 '793 PATENT

20. U.S. Patent No. 10,716,793 was applied for on April 16, 2021, and granted on November 28, 2023.<sup>16</sup> The title and abstract of the patent read:

##### **Treprostinil administration by inhalation**

##### **Abstract**

Treprostinil can be administered using a metered dose inhaler. Such administration provides a greater degree of autonomy to patients. Also disclosed are kits that include a metered dose inhaler containing a pharmaceutical formulation containing Treprostinil.<sup>17</sup>

21. The '793 Patent contains a single independent claim and 8 dependent claims. These claims read as follows:

1. A method of treating pulmonary hypertension comprising administering by inhalation to a human suffering from pulmonary hypertension a therapeutically effective single event dose of a formulation comprising treprostinil or a

<sup>14</sup> Liquidia 10-K, 2022, p. 14.

<sup>15</sup> Liquidia Corporation Form 10-K for the year ending December 31, 2023 ("Liquidia 10-K, 2023"), p. 81.

<sup>16</sup> U.S. Patent 11,826,327.

<sup>17</sup> U.S. Patent 10,716,793.

Non-Confidential

pharmaceutically acceptable salt thereof with an inhalation device, wherein the therapeutically effective single event dose comprises from 15 micrograms to 90 micrograms of treprostinil or a pharmaceutically acceptable salt thereof delivered in 1 to 3 breaths.

2. The method of claim 1, wherein the inhalation device is a soft mist inhaler.
3. The method of claim 1, wherein the inhalation device is a pulsed ultrasonic nebulizer.
4. The method of claim 1, wherein the inhalation device is a dry powder inhaler.
5. The method of claim 1, wherein the inhalation device is a pressurized metered dose inhaler.
6. The method of claim 4, wherein the formulation is a powder.
7. The method of claim 6, wherein the powder comprises particles less than 5 micrometers in diameter.
8. The method of claim 1, wherein the formulation contains no metacresol.<sup>18</sup>

22. I understand that UTC previously obtained a judgment that Liquidia's Yutrepia product would infringe certain claims of the '793 patent.<sup>19</sup> I also understand that the judgment precluded final approval by the FDA of Liquidia's New Drug Application for Yutrepia before the expiration of the '793 patent.<sup>20</sup> I understand that prior to the entry of that judgment, the Patent Trial and Appeal Board invalidated the infringed claims of the '793 patent as obvious.<sup>21</sup> I understand that the Federal Circuit affirmed the PTAB's decision in February 2023.<sup>22</sup> On March 28, 2024, the district court entered an order amending its prior judgment, lifting the injunction precluding final approval of Liquidia's New Drug Application for Yutrepia by the FDA.<sup>23</sup>

#### 4.4 REQUEST FOR A STAY

23. It is my understanding that Liquidia is currently preparing to sell its inhaled dry powder formulation of Treprostinil, Yutrepia, in the United States when permitted by the U.S. Food and Drug

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<sup>18</sup> U.S. Patent 10,716,793.

<sup>19</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755 (RGA), Doc. No. 436.

<sup>20</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755 (RGA), Doc. No. 436.

<sup>21</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755 (RGA), Doc. No. 479.

<sup>22</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755 (RGA), Doc. No. 479.

<sup>23</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, C.A. No. 20-755 (RGA), Doc. No. 479.

Non-Confidential

Administration (“FDA”) after April 1, 2024.<sup>24</sup> I further understand that Yutrepia has been tentatively approved by the FDA for Pulmonary Arterial Hypertension (“PAH”) indication. I also understand that an amendment of the New Drug Application (NDA) for Yutrepia for the Pulmonary Hypertension – Interstitial Lung Disease (“PH-ILD”) indication is currently pending before the FDA.<sup>25</sup>

24. I understand that UTC is requesting a stay of the district court’s amended judgment that lifted the injunction precluding final approval of Liquidia’s New Drug Application for Yutrepia by the FDA.<sup>26</sup> I understand that, if granted, the stay would extend through this Federal Circuit appeal.<sup>27</sup>

#### 4.5 TIMELINE OF EVENTS

25. The following chart provides a timeline showing key dates for UTC and Liquidia.

**Table 3: Timeline of Events**

UTC	Liquidia
2002: Remodulin received FDA approval for subcutaneous administration and began being sold commercially <sup>28</sup>	
2004: Remodulin approved for intravenous administration. <sup>29</sup>	
July 2009: Tyvaso (nebulized) received FDA approval for PAH. <sup>30</sup>	
2013: Orenitram received FDA approval. <sup>31</sup>	
	July 26, 2018: Liquidia started trading on NASDAQ <sup>32</sup>

<sup>24</sup> Liquidia 10-K, 2023, pp. 4–5.

<sup>25</sup> 7.24.23 Liquidia Notice Letter to UTC.pdf.

<sup>26</sup> *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, Case No. 2024-1658 (Fed. Cir.), Doc. No. 11.

<sup>27</sup> *United Therapeutics Corp. v. Liquidia Technologies, Inc.*, Case No. 2024-1658 (Fed. Cir.), Doc. No. 11.

<sup>28</sup> UTC 10-K, 2023, p. 5

<sup>29</sup> UTC 10-K, 2023, p. 5

<sup>30</sup> UTC 10-K, 2023, p. 4; United Therapeutics Announces FDA Approval and Launch of Tyvaso® for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease, PR NEWswire (4/1/2021), (LIQ\_24-1658\_Appeal\_0000372-374), available at <https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html>.

<sup>31</sup> UTC 10-K, 2023, p. 6

<sup>32</sup> Liquidia Technologies Announces Pricing of Initial Public Offering, Liquidia (7/25/2018), (LIQ\_24-1658\_Appeal\_0000371-371), available at <https://www.liquidia.com/news-releases/news-release-details/liquidia-technologies-announces-pricing-initial-public-offering>.

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	January 2020: Liquidia submitted NDA to FDA for Yutrepia approval. <sup>33</sup>
June 2020: Suit filed against Yutrepia in late 2021 for infringement of '901 and '066 Patents ('901 dropped Dec '21 after claim construction). <sup>34</sup> July 2020: '793 Patent added to suit. <sup>35</sup>	
December 2020: Study completed, which "demonstrated the safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution." <sup>36</sup>	
January 2021: Study announced (completed October 2020) showing "comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution." <sup>37</sup> March 31, 2021: Tyvaso (nebulized) received FDA approval for PH-ILD. <sup>38</sup> UTC announced the approval the following day (April 1, 2021). <sup>39</sup> April 16, 2021: '327 Patent filed. <sup>40</sup>	November 5, 2021: Yutrepia received tentative FDA approval for PAH. <sup>41</sup>
August 2021: IPR Proceedings related to '793 Patent began. <sup>42</sup>	

<sup>33</sup> UTC 10-K, 2023, p. 15.

<sup>34</sup> Liquidia 10-K, 2022, p. 65.

<sup>35</sup> Liquidia 10-K, 2022, p. 65.

<sup>36</sup> United Therapeutics Corporation Form 10-K for the year ended December 31, 2022 ("UTC 10-K, 2022"), p. 5.

<sup>37</sup> UTC 10-K, 2022, p. 5.

<sup>38</sup> FDA, TYVASO Approval Package (3/21/2021), (LIQ\_24-1658\_Appeal\_0000001-090), available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2021/022387Orig1s017.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/022387Orig1s017.pdf)

<sup>39</sup> Press Release, United Therapeutics Corp., United Therapeutics Announces FDA Approval and Launch of Tyvaso® For The Treatment Of Pulmonary Hypertension Associated With Interstitial Lung Disease (4/1/2021), (LIQ\_24-1658\_Appeal\_0000095-098), available at <https://pipeline.unither.com/wp-content/uploads/2021/05/2021-04-01-INCREASE-approval-FINAL-formatted.pdf>

<sup>40</sup> U.S. Patent 11,826,327.

<sup>41</sup> Liquidia Website, Pipeline (LIQ\_24-1658\_Appeal\_0000370-370), <https://www.liquidia.com/products-and-pipeline/overview>.

<sup>42</sup> UTC 10-K, 2023, p. 16.

Non-Confidential

May 23, 2022: Tyvaso DPI received FDA approval for both PAH and PH-ILD. <sup>43</sup> UTC announced approval following day (May 24, 2022). <sup>44</sup>	
June 2022: Tyvaso DPI launched commercially. <sup>45</sup>	
July 19, 2022: IPR proceedings on the ‘793 Patent found all claims unpatentable. <sup>46</sup>	
August 31, 2022: District court found Liquidia’s product would infringe ‘793 Patent. (‘066 found partially invalid and partially not infringed) <sup>47</sup>	
July 2023: Appellate court affirmed district court ruling on ‘793 Patent. <sup>48</sup>	
September 5, 2023: New suit filed on ‘793 Patent related to PH-ILD indication <sup>49</sup>	
November 28, 2023: ‘327 Patent issued. <sup>50</sup>	
November 30, 2023: Amended complaint added ‘327 patent. <sup>51</sup>	
December 20, 2023: Federal Circuit affirmed IPR decision to invalidate claims of ‘793 Patent. <sup>52</sup>	
January 22, 2024: ‘793 Patent from withdrawn from suit. <sup>53</sup>	
February 20, 2024: UTC filed lawsuit against FDA. <sup>54</sup>	

<sup>43</sup> FDA, NDA 214324 Approval Letter (5/23/2022), available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2022/214324Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214324Orig1s000ltr.pdf)

<sup>44</sup> Press Release, United Therapeutics Corp., United Therapeutics Announces FDA Approval Of Tyvaso DPI™ (5/24/2022) (LIQ\_24-1658\_Appeal\_0000099-102), available at <https://ir.unither.com/~media/Files/U/United-Therapeutics-IR/documents/press-releases/2022/2022-05-24-DPI-approval-FINAL-formatted.pdf>

<sup>45</sup> UTC 10-K, 2023, p. 4

<sup>46</sup> UTC 10-K, 2023, p. 16; *United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1364 (Fed. Cir. 2023), available at [https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023\\_2161663.pdf](https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023_2161663.pdf), p. 4.

<sup>47</sup> UTC 10-K, 2023, p. 15; *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. 23-804, 2024 WL 305626, at \*9 (U.S. Jan. 23, 2024) (LIQ\_24-1658\_Appeal\_0000147-369), available at [https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555\\_23-PetitionForAWritOfCertiorari.pdf](https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-PetitionForAWritOfCertiorari.pdf).

<sup>48</sup> UTC 10-K, 2023, p. 15.

<sup>49</sup> UTC 10-K, 2023, p. 16.

<sup>50</sup> U.S. Patent 11,826,327.

<sup>51</sup> UTC 10-K, 2023, p. 16.

<sup>52</sup> Press Release, Liquidia Technologies, Inc., U.S. Federal Circuit Affirms Earlier PTAB Decision to Invalidate All Claims of United Therapeutics Patent No. 10,716,793 (‘793 Patent), (12/20/2023) (LIQ\_24-1658\_Appeal\_0000390-391), available at <https://liquidia.com/news-releases/news-release-details/us-federal-circuit-affirms-earlier-ptab-decision-invalidate-all>

<sup>53</sup> UTC 10-K, 2023, p. 16.

<sup>54</sup> UTC 10-K, 2023, p. 16.

Non-Confidential

March 12, 2024: Federal Circuit declined UTC's request to rehear decision affirming IPR decision invalidating claims of '793 Patent. <sup>55</sup>
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March 2024: UTC FDA clinical trial exclusivity for PH-ILD set to expire <sup>56</sup>
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March 28, 2024: District Court vacates judgment of infringement on the '793 patent and vacates order blocking final approval of Liquidia's NDA. <sup>57</sup>
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## 5. OVERVIEW OF THE SELCK DECLARATION

26. Dr. Selck offers opinions regarding the harms he believes UTC will suffer absent a stay including:

- Two forms of direct harm (price erosion and lost sales)
- Three forms of consequential harm (lost first mover advantage, reduced pipeline and reputational harm.)
- Irreparability of the harms.
- Balance of equities.
- Public interest.

27. In the following sections, I first discuss how Dr. Selck's opinions about the direct harms are refuted by UTC management's statements and forecasts, followed by sections specifically addressing each of his opinions.

## 6. EVIDENCE FROM UTC

28. Evidence from UTC's management indicates that Liquidia's sales of Yutrepia are not expected to affect UTC's sales of Tyvaso. In particular, the evidence shows that UTC does not believe that it will be harmed by Yutrepia's launch.

29. In the sections below, I first discuss a forecast of Tyvaso sales generated by UTC in [REDACTED]. I then highlight statements from UTC's management discussing the expected effect of Yutrepia's launch. Finally, I analyze investor sentiment

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<sup>55</sup> Press Release, Liquidia Technologies, Inc., Liquidia Corporation Reports Full Year 2023 Financial Results and Provides Corporate Update (3/13/2024) (LIQ\_24-1658\_Appeal\_0000091-094), available at <https://liquidia.com/news-releases/news-release-details/liquidia-corporation-reports-full-year-2023-financial-results>

<sup>56</sup> UTC 10-K, 2023, p. 16.

<sup>57</sup> *United Therapeutics Corp. v. Liquidia Techs., Inc.*, Case No. 1:20-cv-00755-RGA, Doc. No. 479 (March 28, 2024).

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through an analysis of stock price movements for Liquidia and UTC around the dates of significant announcements.

## 6.1 UTC FORECAST

30. UTC's own [REDACTED] forecast demonstrates that [REDACTED]  
[REDACTED] UTC would be able to [REDACTED].<sup>58</sup>

31. Notably, this [REDACTED]  
[REDACTED]<sup>59</sup> The forecast was [REDACTED] July 2023 Liquidia letter  
notifying UTC that it had submitted an amendment to its NDA to the FDA to add the PH-ILD indication  
to its label for Yutrepia.<sup>60</sup> UTC's forecast [REDACTED]

[REDACTED]  
[REDACTED].<sup>61</sup>

32. This is the [REDACTED] forecast produced by UTC in this matter.

33. UTC's price for of a single dose of Tyvaso increased at 5% per year between 2009 and 2023 as  
shown in the chart below. For points of reference, the price of Tyvaso in 2023 was [REDACTED]  
[REDACTED] for Tyvaso TD-300 and [REDACTED] for Tyvaso DPI.<sup>62</sup>

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<sup>58</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0102, 0105.

<sup>59</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0107.

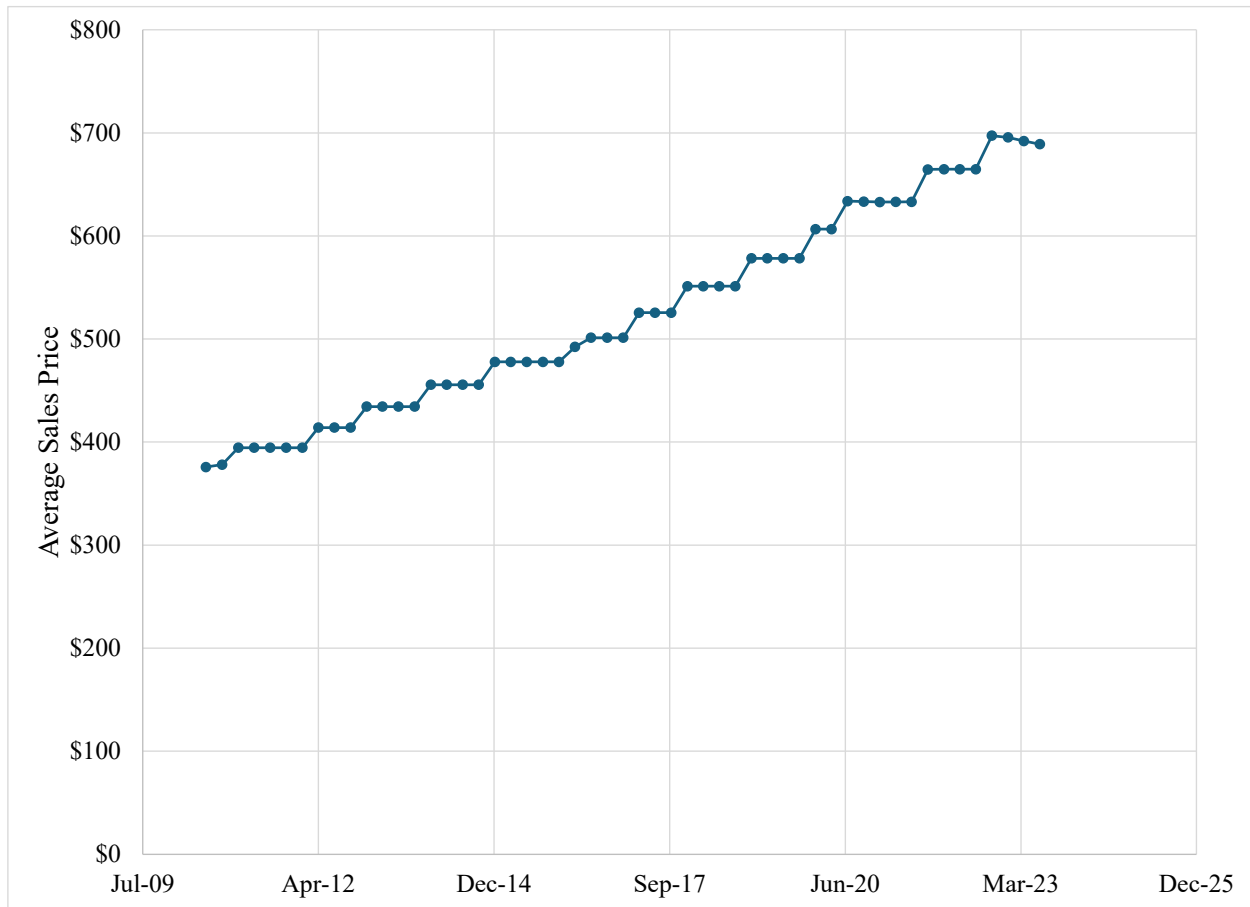
<sup>60</sup> 7.24.23 Liquidia Notice Letter to UTC.pdf.

<sup>61</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0107 (highlighting added).

<sup>62</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0102.



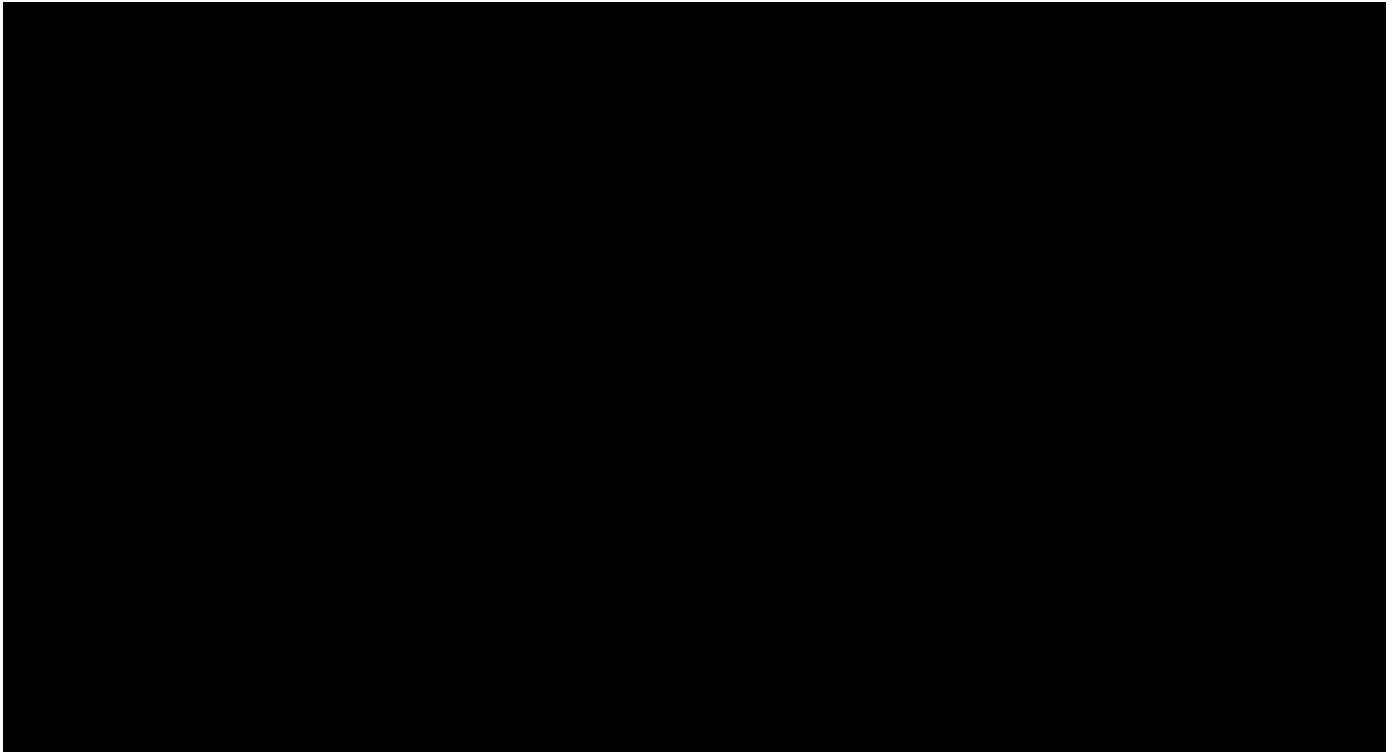
**Chart 4: Average Sales Price per 1.74-MG Dose of Tyvaso<sup>63</sup>**



34. This growth is [REDACTED] UTC forecasted that [REDACTED]  
 [REDACTED]:

<sup>63</sup> Exhibit 3. United CMS ASP Data. This does not include Tyvaso DPI. I do not currently have information explaining why the price of Tyvaso declined from \$697 per dose to \$689 per dose between the fourth quarter of 2022 and the third quarter of 2023.

**Chart 5: Annual Price for Tyvaso (Forecast) <sup>64</sup>**



35. UTC is forecasting that [REDACTED]  
[REDACTED]. UTC estimates that [REDACTED]  
[REDACTED] <sup>65</sup> However, it is also forecasting that [REDACTED]  
[REDACTED]. <sup>66</sup> Thus, the  
[REDACTED]  
[REDACTED] <sup>67</sup> Combining the [REDACTED]  
[REDACTED]. <sup>68</sup>

36. UTC is forecasting that [REDACTED]  
[REDACTED] UTC estimates that [REDACTED] in the United  
States. <sup>69</sup> UTC forecasted that [REDACTED]

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<sup>64</sup> Exhibit 4. UTC 2023 Forecast.

<sup>65</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101, 0104.

<sup>66</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101, 0104.

<sup>67</sup> [REDACTED]. UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101, 0104.

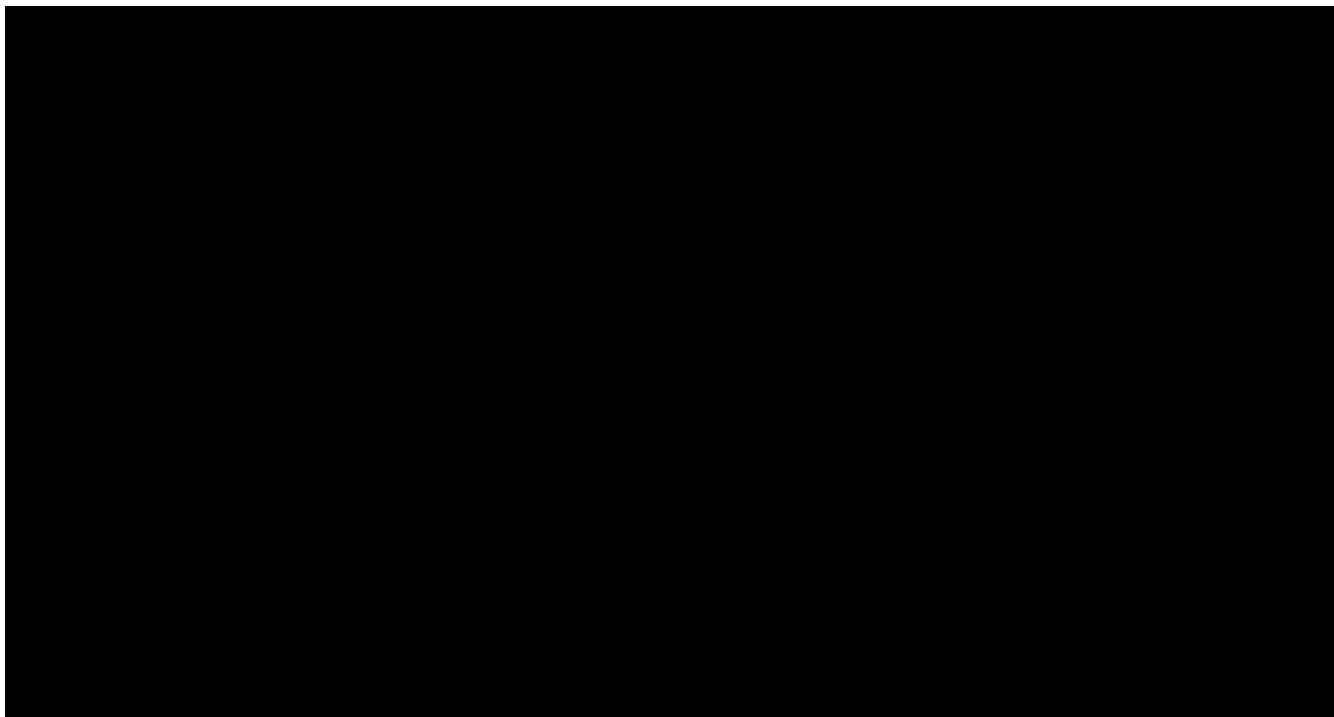
<sup>68</sup> [REDACTED] UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101.

<sup>69</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101, 0104.

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[REDACTED]<sup>70</sup> Note that UTC projects a [REDACTED]  
[REDACTED] and then [REDACTED]  
[REDACTED]

**Chart 6: UTC Forecasted Tyvaso Patients<sup>71</sup>**



37. UTC is, therefore, projecting [REDACTED]  
[REDACTED]<sup>72</sup>

38. As a result of [REDACTED], UTC is forecasting revenue from sales of Tyvaso for PAH and PH-ILD to [REDACTED]

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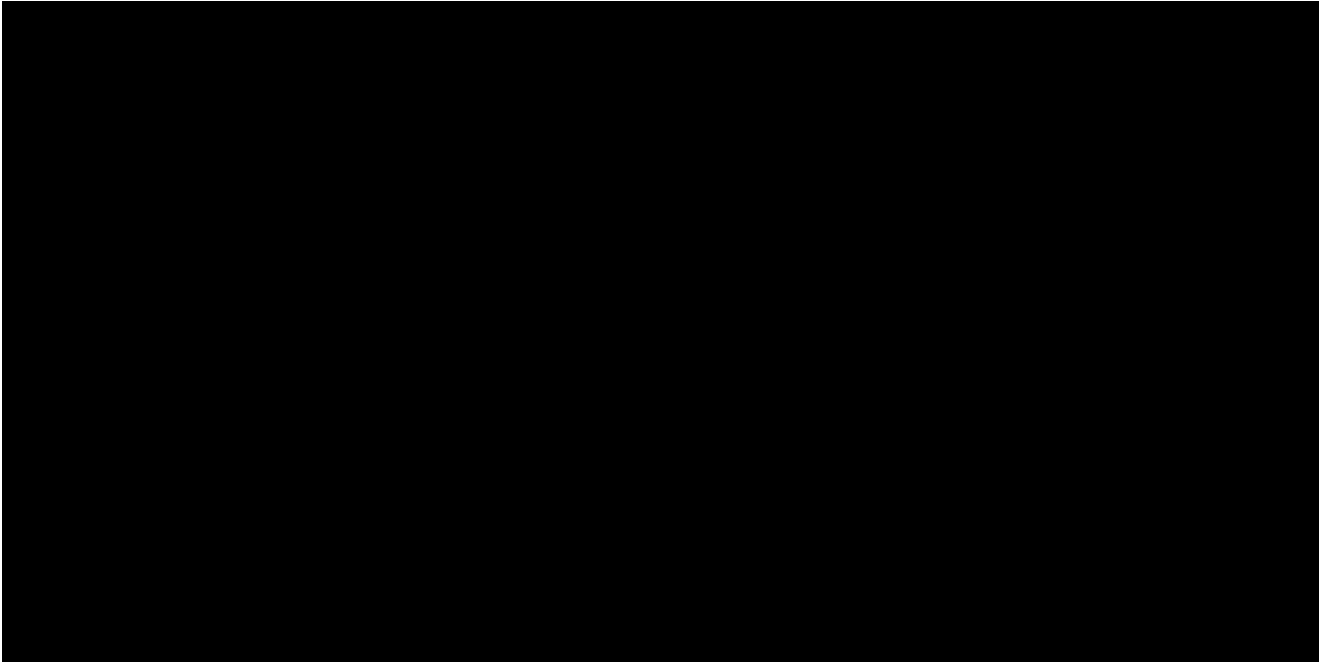
<sup>70</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101.

<sup>71</sup> Exhibit 4. UTC 2023 Forecast; UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101.

<sup>72</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0107.

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**Chart 7: UTC Forecasted Revenues from Tyvaso<sup>73</sup>**



39. In summary, UTC forecasted that it would [REDACTED]

[REDACTED]<sup>74</sup>

## **6.2 UTC MANAGEMENT'S STATEMENTS**

40. In contrast to Dr. Selck's opinion, UTC management has not projected any loss in revenue due to the launch of Yutrepia. In fact, UTC's public statements, before and after filing the present motion for a stay, suggest that it does not expect any harm from the launch of Yutrepia.

41. In an earnings call on February 22, 2023 discussing UTC's results for the fourth quarter of 2022, UTC's Founder, Chairman & CEO, Martine Rothblatt was asked about the introduction of another potential option for treating PAH (sotarcept) and answered as follows:

I will say that our revenue forecast is agnostic with regard to whether or not sotatercept is approved or not. In other words, we will remain confident about achieving the doubling of our revenues by 2025 without regard to its launch. There -- it's a very large and diversely treated patient population. Changes in treatment patterns are relatively slow and cautious especially other than frontline treatments such as like ETRAs or PD5s. So I'd be very, very skeptical that you would see an impact of sotatercept on United Therapeutics revenue profile or product uptake across the board, whether it's Remodulin, Tyvaso, Tyvaso DPI or Orenitram.

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<sup>73</sup> Exhibit 4. UTC 2023 Forecast.

<sup>74</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0102, 0105.

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**More broadly, the experience has been that when new agents have been introduced into the market, it has grown the market for all of the existing patients.** It's kind of like a market growth thing. You saw this with, for example, back in the day when we launched Remodulin and J&J's precursor Actelion launched bosentan, the treprostinil revenues did not shrink. In fact, they grew and then later on, when PDSs were introduced, the market for ETRAs, and treprostinil did not shrink. In fact, it grew, it grew quite a bit. And this has been just a continuous process, and it harkens back to the landmark number that you should keep in your mind that Michael Benkowitz mentioned in his remarks was 50,000, that's 5-0 thousand. That's the number of patients diagnosed with pulmonary hypertension. And all of these drugs have just like scratched the surface of being able to really treat the patients and get them back to a New York Heart Association Functional Class I or even Functional Class II level.

**So there is so much robust room for growth and improvement in pulmonary hypertension. We at United Therapeutics, welcome any new agent that can help the health of the pulmonary hypertension patient population.** And by the way, all that is with respect to WHO Group I pulmonary hypertension. So everything I just said, then you've got this other huge pool that Dr. Peterson opened up with her New England Journal article, WHO Group 111, 30,000 patients, that's 3-0 thousand, of which the only approved treatment right now is our Tyvaso drug.

And I think sotatercept, I would love to see another good drug to help people with pulmonary hypertension. I don't think it's going to have any effect on our revenue growth.<sup>75</sup>

42. In an earnings call on May 3, 2023 discussing UTC's results for the first quarter of 2023, in her opening remarks, Dr. Rothblatt stated:

Thank you, Dewey. Very excited to welcome everyone to another great quarter at United Therapeutics. We are thrilled to continue on course toward our mid-decade goals of 25,000 patients being treated for pulmonary hypertension and the doubling of our revenue run rate. This quarter, we moved toward those goals with double-digit revenue growth from first quarter '22 to first quarter '23. And that also includes, by the way, nearly 40% growth in our main growth driver, which is Tyvaso.

**I think our double-digit growth rate remains a solid forecast even with the possibility of new FDA approvals of sotatercept or Liquidia.** The reason is that sotatercept has not even been tested in our main growth market of Group 3 pulmonary hypertension. Indeed, systemic drugs are generally contraindicated there due to them causing V/Q or ventilation-perfusion mismatch. In the disease sotatercept was tested in, Group 1 pulmonary arterial hypertension, we expect it

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<sup>75</sup> LIQ 24-1658 Appeal\_0000103-113 at 111-112 [Refinitiv Edited Transcript UTHR.0Q - Q4 2022 United Therapeutics Corp Earnings Call, February 22, 2023] (**Emphasis** added).

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to be complementary to either our Orenitram, Tyvaso or Remodulin products. So we don't forecast a realistic threat from sotatercept to our growth.

(inaudible) **Liquidia, if approved, also does not challenge our projected double-digit growth.** It's because it's not a generic product, but is instead a strongly differentiated drug device product requiring 65% more drug to even match Tyvaso's effect based on their own clinical trial data.<sup>76</sup>

43. In an earnings call on August 2, 2023 discussing UTC's results for the second quarter of 2023, UTC was asked about the PH-ILD indication and UTC's President & COO, Michael Benkowitz answered:

[Q.] Maybe just as we think about penetration into the PH-ILD market, where do you think you stand now? And now that the therapy has been on the market for a couple of years in the indication, have your expectations for the size of this market changed at all?

[A.] Sure. I think on penetration of the market, I think we're in low single digits. And I say think because I still -- and this is, I think, a question that was asked earlier that we just didn't have time to ask, but around the kind of the mix of the PAH and the PH-ILD. I mean the data coming in on the referrals is still not -- [not target], it's still a little dirty. So it's not still 100% clean in terms of what's Group 1 or what's Group 3. But I think based on kind of what we're seeing, it's -- I think it's fair to say that we're kind of in that low single digits of the PH-ILD market.

And in terms of the size of the market, nothing's really changed in terms of our understanding of what that is. We kind of started out saying it's at least 30,000. We still think that that's accurate. You can talk to some KOLs, you'd think it's significantly higher than that, and that may be. But what we've said all along with the 30,000, I mean that's still a really good size market for us. And so we're really focused on continuing to penetrate in that market. And get -- as I said in my opening remarks, really kind of ramp up the screening of ILD patients to look for pulmonary hypertension.<sup>77</sup>

44. At a March 5, 2024 conference, Mr. Benkowitz was asked about how UTC sees Liquidia as a potential competitor and whether it was factored into UTC's business model. Mr. Benkowitz responded that based on discussions with payers (e.g., insurance companies), UTC believes that Tyvaso and Yutrepia will be competing on "a level playing field" where the doctor and patient will decide which treatment to use:

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<sup>76</sup> LIQ\_24-1658\_Appeal\_0000114-124 at 116 [Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023]. **Emphasis** added.

<sup>77</sup> LIQ\_24-1658\_Appeal\_0000125-136 at 133 - 134 [Refinitiv Edited Transcript UTHR.0Q - Q2 2023 United Therapeutics Corp Earnings Call, August 2, 2023].

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Did you say why would Liquidia become the -- I think I believe -- we believe Tyvaso will continue to be the preferred agent for very -- I mean the big one is that we've got 2 years of patient data, thousands of patients on the product. The patients are -- satisfaction level is incredibly high both by the physicians and by the patients. And so they have that experience with our product, which is incredibly helpful.

I think -- we think the convenience of our device as a differentiator. Ours is one (inaudible) per session. Their's 2. Ours doesn't require cleaning. Their's does. We don't have a max label dose. And so we just think, all in all, the patients and the physicians are going to prefer our product. We think the other thing that's attractive about our devices are just what's called a low-flow device and so that means that it requires less patient effort to actually breed [sic] the drug. And then as a result of that, that property or that characteristic. The drug is actually getting deeper into the lungs. So what you see with a high flow device, which is what their device is. So we think all in all, the totality of the characteristics of our device are going to be preferred by physicians and patients.

**And then on the payer side, you were in these discussions right now with payers and kind of working that out. But I think we're feeling increasingly confident that there's not going to be preference, so it's going to be a level playing field. So it's really going to be up to the patient and the physician, and we feel confident about how we're going to do there.**<sup>78</sup>

45. UTC management, therefore, based on statements over the past several years does not appear to believe that its revenue is threatened by the launch of Yutrepia. It is forecasting and publicly stating that it still expects “double-digit” revenue growth for UTC even after Yutrepia’s launch.

### 6.3 STOCK PRICE ANALYSIS

46. Dr. Selck claims that:

Recent stock price trends further demonstrate the competitive relationship between United and Liquidia. Around December 20, 2023, when the Federal Circuit affirmed a PTAB decision that would hold all claims of the '793 patent are not patentable, United's stock price dropped significantly and Liquidia's stock price increased significantly. From an economic perspective, United's stock price decreasing and Liquidia's stock price increasing around this event demonstrate that the market views Yutrepia and the Tyvaso products to be close competitors. This stock price behavior is indicative of investor expectations of direct competition between Yutrepia and the Tyvaso products.<sup>79</sup>

<sup>78</sup> LIQ\_24-1658\_Appeal\_0000137-146 at 142 [Refinitiv StreetEvents, Edited Transcript, UTHR.0Q - United Therapeutics Corp at TD Cowen Health Care Conference, March 05, 2024, p. 6] (**emphasis added**).

<sup>79</sup> Selck Declaration, ¶57.

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47. While I agree with Dr. Selck that Tyvaso and Yutrepia are competitors, his evidence from the stock market is both flawed and incomplete.

48. His analysis is flawed for several reasons:

- Use of a four-day event window
- Failure to normalize for overall market movements
- Failure to analyze whether the movement is statistically significant.

49. The four-day event window is far longer than the market requires to respond to news and, therefore, will incorporate movements unrelated to the news. In particular, Dr. Selck's four-day window spans across a weekend. UTHR's price changed by -6.1%, -3.2% 0.3%, -1.2% respectively on the four days including and after December 20, 2023.<sup>80</sup> There is no reason to believe that UTC's stock price increased by 0.3% on the third day due to the news that the Federal Circuit decided to invalidate one of its patents. Restricting the event window to just December 20, 2023 suggests that UTC's stock price declined by 6.1% due to the news.

50. In fact, the news that the Federal Circuit had invalidated all claims of the '793 Patent was apparently incorporated into UTC's stock price within fifteen minutes. The Federal Circuit typically publishes its opinions between 8:30am and 11:00am (Eastern) each day.<sup>81</sup> The intraday chart of UTHR shows that it first traded at 9:30am at \$240 and fell below \$230 by 9:45am, then drifted down to close at \$225 as shown in the chart below:

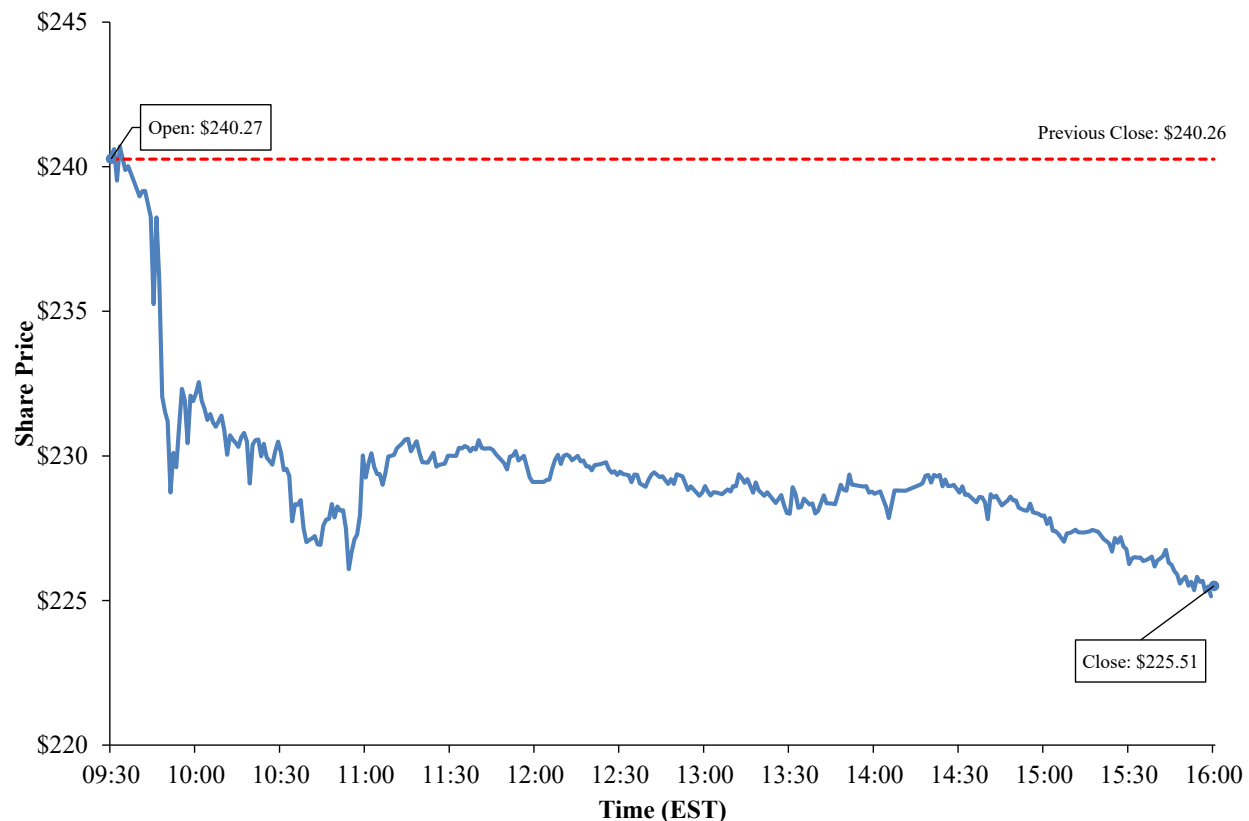
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<sup>80</sup> Exhibit 5.2.

<sup>81</sup> U.S. Court of Appeals for the Federal Circuit, Opinions and Orders (LIQ\_24-1658\_Appeal\_0000394-396), available at <https://cafc.uscourts.gov/home/case-information/opinions-orders/>.



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**Chart 8: UTHR Intraday Price, 20 December 2023<sup>82</sup>**

Source: Price data from Thomson Reuters.

51. Therefore, there is no basis for Dr. Selck to use a four-day event window when it appears that the news had been incorporated into UTC's stock price within fifteen minutes.

52. Dr. Selck also fails to normalize for overall market movements. For example, on the day of the announcement, December 20, 2023, the overall NASDAQ 100 index declined by 1.5%. Thus, the price movement on December 20, 2023 that might be due to the news is only -4.6%.<sup>83</sup>

53. Dr. Selck also does not investigate whether this movement on December 20, 2023 is statistically significant. Stock prices move every day due to a wide variety of factors. Statisticians use a significance test to see whether the stock price movement on any single day is more than two standard deviations away from the average.<sup>84</sup>

<sup>82</sup> Exhibit 6. Intraday Chart UTHR.

<sup>83</sup> Exhibit 5.2.

<sup>84</sup> A standard deviation is a measure of the spread of data around the mean. Two standard deviations away from the mean indicates that the data point is unusually far from the mean and may be significantly different from the

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54. Dr. Selck's work is incomplete in the sense that he only examines this one event without considering UTC's and Liquidia's stock price movements around other events.

55. My more-sophisticated analysis of UTC's and Liquidia's stock prices indicates that there was a statistically significant change in both UTC's and Liquidia's stock prices on December 20, 2023.<sup>85</sup> Note that I am not claiming that my analysis is definitive. Doing a full and complete analysis of any particular event on stock prices is a lengthy and detailed endeavor involving a careful examination of the exact time when the news became available, the typical amount of time it takes for the market to react to the news (the event window) and an analysis of confounding factors that could have caused or contributed to the price movement.<sup>86</sup> In this case, given the time constraints, I believe my analysis is generally accurate but additional evidence could be brought to my attention that might lead me to change my conclusions.

56. My more fulsome analysis of news that might have affected both UTC (ticker symbol "UTHR") and Liquidia (ticker symbol "LQDA") stocks indicates that UTC's stock price is less sensitive to announcements than Liquidia's. In the table below figures in red indicate that the stock price movement was statistically significant.

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average. I am using two standard deviations here because that is a typical significance test at the 95% confidence level.

<sup>85</sup> Exhibit 5.1.

<sup>86</sup> A confounding factor in statistics is an additional factor that could affect the stock price – e.g. perhaps an announcement by some other pharmaceutical company that would affect investor's perceptions of either UTC's or Liquidia's prospects.

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**Table 9: Normalized Stock Price Changes on Selected Dates<sup>87</sup>**

<b>Date</b>	<b>Event</b>	<b>LQDA</b>	<b>UTHR</b>
31-Mar-2021	Tyvaso (nebulized) receives FDA approval for PH-ILD indication	5.9%	1.1%
01-Apr-2021	UTC announces Tyvaso FDA approval for PH-ILD	2.6%	15.0%
05-Nov-2021	Yutrepia receives tentative FDA approval for PAH indication	-4.2%	0.4%
08-Nov-2021	Liquidia announces tentative FDA approval for PAH indication	4.1%	-0.1%
23-May-2022	Tyvaso DPI receives FDA approval	-18.8%	11.6%
24-May-2022	UTC announces Tyvaso DPI FDA approval	-28.3%	4.2%
19-Jul-2022	PTAB issues decision finding all claims of '793 Patent unpatentable	45.3%	-1.1%
30-Aug-2022	Judge denies stay of decision on '793 Patent pending PTAB appeal	-30.4%	0.7%
31-Aug-2022	Court ruling against '793 Patent	7.2%	3.5%
01-Sep-2022	Liquidia shareholder call regarding ruling on '793 Patent	-15.8%	-0.2%
20-Dec-2023	Federal Circuit affirms PTAB decision to invalidate '793 Patent	35.7%	-6.1%

57. The table above indicates that UTC's stock generally was unaffected by rulings in the prior patent case – other than the December 20, 2023 announcement – while it was positively affected by announcements relating to approval of Tyvaso DPI and the PH-ILD indication. In particular, the PTAB decision on July 19, 2022 invalidating all claims of the '793 Patent does not appear to have affected UTC's stock price; which is a contrast to the Federal Circuit ruling on December 20, 2023. Additionally, the news that Yutrepia had received FDA approval did not affect UTC's stock price – nor did it significantly affect Liquidia's stock price.

58. Liquidia's stock, on the other hand, has been significantly affected by rulings in the prior patent case as well as the launch of Tyvaso DPI.

## **7. PRICE EROSION**

59. Dr. Selck's opinion is based on a general discussion of price erosion in pharmaceuticals and an undocumented interview lasting less than an hour of a UTC employee who generally claimed [REDACTED]

[REDACTED].<sup>88</sup> Dr. Selck reviews the

<sup>87</sup> Exhibit 5.1. "Normalized" figures account for overall market movements.

<sup>88</sup> Selck Declaration, ¶¶58, 60.

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history of price declines for Hepatitis C treatments<sup>89</sup>, and PCSK9 Inhibitors<sup>90</sup> after the entry of competitors. However, Dr. Selck then opines that these examples are not instructive in the present case:

While the outcome of direct competition between products in other markets (e.g., PCSK9 inhibitors or Hepatitis C treatments) may provide insight as to the types of harm that United is likely to suffer absent a stay on Yutrepia's approval and entry (i.e., price erosion, lost sales, and lost market share), as well as demonstrating that such harms can be significant, the PAH and PH-ILD markets are unique such that the experience of other products is a deficient benchmark for quantifying the full extent of the impact of Liquidia's infringement on United.<sup>91</sup>

...

A similar logic applies to other potential benchmarks. There is no comparable that is a close enough comparator to the circumstances of Tyvaso and Tyvaso DPI.<sup>92</sup>

60. I agree with Dr. Selck that price erosion can happen with competitive entry and that it does appear to have happened in the two cases he cites. I also agree with Dr. Selck that no further conclusions can be drawn from his two examples. However, that does not answer the critical question of whether, or if, price erosion will happen if Yutrepia is allowed to enter the market.

61. The evidence Dr. Selck proffers for price erosion specifically linked to launching Yutrepia with a PH-ILD indication comes entirely from a single, undocumented interview with UTC's "Associated [sic] Vice President of Managed Markets and Reimbursement", David Barton.<sup>93</sup> Dr. Selck relies on Mr. Barton for the following assertions:

[REDACTED]

.<sup>94</sup>

...

[REDACTED]

.<sup>95</sup>

...

[REDACTED]

<sup>89</sup> Selck Declaration, ¶¶72–76, 86–87.

<sup>90</sup> Selck Declaration, ¶¶77–79, 86–87.

<sup>91</sup> Selck Declaration, ¶117.

<sup>92</sup> Selck Declaration, ¶119.

<sup>93</sup> Selck Declaration, ¶10.

<sup>94</sup> Selck Declaration, ¶58.

<sup>95</sup> Selck Declaration, ¶60.

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[REDACTED]  
96

...  
[REDACTED]  
97

...  
[REDACTED]  
98

...  
[REDACTED]  
99

62. I have been unable to ascertain from Dr. Selck's conclusory statements from his undocumented conversation with Mr. Barton regarding [REDACTED]

63. In summary, according to UTC's own documents and statements, price erosion due to Yutrepia's launch does not appear to be a discernible threat to UTC. While price erosion can occur in theory, neither of Dr. Selck's examples are useful here. His only evidence supporting price erosion due to Yutrepia's launch comes from a single, undocumented conversation with a UTC employee. But that conversation only indicated Mr. Barton's belief that [REDACTED]

## **8. LOST SALES**

64. I agree with Dr. Selck that Tyvaso and Yutrepia will compete for patients. However, UTC's management's statements and forecasts indicate that Tyvaso is not expecting much, if any, loss of patients due to Yutrepia's launch.

65. Dr. Selck's opinions on lost sales appear to assume that every Yutrepia patient will be a lost Tyvaso patient. Dr. Selck does not offer any evidence to support this conclusion, and it is questionable given that UTC [REDACTED] and that it will

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<sup>96</sup> Selck Declaration, ¶60.

<sup>97</sup> Selck Declaration, ¶62.

<sup>98</sup> Selck Declaration, ¶68.

<sup>99</sup> Selck Declaration, ¶69.

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██<sup>100</sup> Consistent with Dr. Rothblatt’s commentary that new agents will expand the market for pulmonary hypertension therapies and UTC’s own forecasts ██████████  
████████████████████, the evidence suggests that Yutrepia could serve some patients that Tyvaso would not be serving.

## **9. LOST FIRST MOVER ADVANTAGE**

66. Dr. Selck opines that UTC will lose its first mover advantage absent a stay:

Through its investments in the Tyvaso products, United has engaged in effort to increase its brand recognition for the Tyvaso products among both physicians and patients. With the Tyvaso products as the first inhaled treprostinil-based therapies in the PAH market, and the only FDA-approved therapies in the PH-ILD market, United has also benefited from first mover advantages in both markets, including brand recognition and stickiness due to patient familiarity.<sup>101</sup>

...  
Liquidia’s premature entry will irreparably harm United through negating United’s first mover advantage benefits including brand recognition. United has expended time and expense developing the Tyvaso products and obtaining approval for the Tyvaso products to treat PAH and PH-ILD, and in doing so effectively created the PH-ILD market segment. As such, United is establishing the brand name of Tyvaso as synonymous with innovation for both PAH and PH-ILD and with filling the unmet need for a treatment for PH-ILD.<sup>102</sup>

67. First, Dr. Selck has not provided any evidence that “United is establishing the brand name of Tyvaso as synonymous with innovation” — that is simply an assertion without any support.<sup>103</sup>

68. Second, it is hard to see how Tyvaso for PAH – which was launched in 2009 and currently treats a small percentage of PAH patients – continues to benefit from any first mover advantage.<sup>104</sup> Presumably, whatever benefits there might have been to being a first mover have been realized. The only conceivable first mover advantage would be tied to the PH-ILD indication. However, given that Tyvaso was approved for PH-ILD three years ago, it is unclear what, if any, additional first mover advantage there might be.<sup>105</sup>

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<sup>100</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)] at 0101, 0104.

<sup>101</sup> Selck Declaration, ¶88.

<sup>102</sup> Selck Declaration, ¶89.

<sup>103</sup> Selck Declaration, ¶89.

<sup>104</sup> Section 6.1; UTC 10-K, 2023, p. 4; United Therapeutics Announces FDA Approval and Launch of Tyvaso® for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease, PR NEWswire (4/1/2021), (LIQ\_24-1658\_Appeal\_0000372-374), available at <https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html>.

<sup>105</sup> See 3/31/2021 Approval Letter

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69. Furthermore, while the idea of a first mover advantage has conventional wisdom behind it, careful reviews indicate that it is not always a given. In fact, the paper Dr. Selck cites most heavily concludes that there are disadvantages to being the first mover:

We first consider theoretical models and empirical evidence on three general categories in which first-mover advantage can be attained: leadership in product and process technology, preemption of assets, and development of buyer switching costs. We then examine potential *disadvantages* of first-mover firms (or conversely, relative advantages enjoyed by late-mover rivals). These include free-rider problems and a tendency toward inertia or sluggish response by established incumbents.<sup>106</sup>

70. Another paper not cited by Dr. Selck describes the first mover advantage as a myth:

**The Myth of First Mover Advantage**

Conventional wisdom would have us believe that it is always beneficial to be first – first in, first to market, first in class. The popular business literature is full of support for being first and legions of would-be business leaders, steeped in the Jack Welch school of business strategy, will argue this to be the case. The advantages accorded to those who are first to market defines the concept of First Mover Advantage (FMA).

We outline why this is not the case, and in fact, that there are conditions of applicability in order for FMA to hold (and these conditions often do not hold). We also show that while there can be advantages to being first, from an economic perspective, the costs generally exceed the benefits, and the full economics of FMA are usually a losing proposition. Finally, we show that increasingly, we live in a world where FMA is eclipsed by innovation and format change, rendering the FMA concept obsolete (i.e. strategic obsolescence).<sup>107</sup>

71. Another paper not cited by Dr. Selck concludes that:

Some management concepts have such intuitive appeal that their validity is almost taken for granted. First-mover advantage is one such concept. Although the fate of its most-convinced adherents, the dot-coms, offers a cautionary lesson, managers' faith that first-mover status brings important competitive advantages, even when network effects are not available to accelerate and entrench it, remains undiminished. Business executives from every kind of company maintain, almost without exception, that early entry into a new industry or product category gives any firm an almost insuperable head start. But for every academic study proving that first-mover advantages exist, there is a study proving they do not. While some well-known first movers, such as Gillette in safety razors and Sony in personal stereos, have enjoyed considerable success, others, such as Xerox in fax machines and eToys in

<sup>106</sup> Lieberman, Marvin B. and David B. Montgomery, "First-Mover Advantages," *Strategic Management Journal* 9, (1988): 41–58, at 41 (emphasis in original).

<sup>107</sup> IHS Consulting, "The Myth of First Mover Advantage", February 2012.

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Internet retailing, have failed. We have found that the differences in outcome are not random—that first-mover status can confer advantages, but it does not do so categorically. Much depends on the circumstances in which it is sought.<sup>108</sup>

72. The fundamental question of why innovators frequently do not reap the benefits of their innovation was addressed in a highly regarded paper written by Dr. David Teece in 1986. Dr. Teece wrote:

This paper attempts to explain why innovating firms often fail to obtain significant economic returns from an innovation, while customers, imitators and other industry participants benefit. Business strategy – particularly as it relates to the firm’s decision to integrate and collaborate – is shown to be an important factor. The paper demonstrates that when imitation is easy, markets don’t work well, and the profits from innovation may accrue to the owners of certain complementary assets rather than to the developers of the intellectual property. This speaks to the need, in certain cases, for the innovating firm to establish a prior position in these complementary assets. The paper also indicates that innovators with new products and processes which provide value to consumers may sometimes be so ill positioned in the market that they necessarily will fail. The analysis provides a theoretical foundation for the proposition that manufacturing often matters, particularly to innovating nations. Innovating firms without the requisite manufacturing and related capacities may die, even though they are the best at innovation.<sup>109</sup>

73. While a first mover advantage is a possibility, it does not appear that, if it exists for UTC’s marketing of Tyvaso, it is significant. The Lieberman article on first mover advantages cited heavily by Dr. Selck suggests that first mover advantages arise from three sources:

- leadership in product and process technology,
- preemption of assets
- development of buyer switching costs<sup>110</sup>

74. The first two sources of first mover advantage do not appear to apply to Tyvaso because Liquidia has, at least arguably, a superior product and there are no assets to preempt here. The final category – the “development of buyer switching costs” appears weak at best. Dr. Selck refers to brand recognition

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<sup>108</sup> Suarez, Fernando and Gianvito Lanzolla, “The Half-Truth of First-Mover Advantage,” *Harvard Business Review*, April 2005 [(LIQ\_24-1658\_Appeal\_0000375-389)].

<sup>109</sup> Teece, David, “Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy,” *Research Policy* 15, (1986): 285–305, at 285.

<sup>110</sup> Lieberman, Marvin B. and David B. Montgomery, “First-Mover Advantages,” *Strategic Management Journal* 9, (1988): 41–58, at 41–42.



Non-Confidential

arising from Tyvaso's sales.<sup>111</sup> However, in a highly regulated environment with a focus on product efficacy and price, it is hard to see how brand recognition would lead to significant buyer switching costs.

75. In summary, while Dr. Selck alludes to the conventional wisdom of a first mover advantage, that is overly simplistic. There are no apparent first mover advantages for Tyvaso related to PAH fifteen years after its launch and, while a first mover advantage for the PH-ILD indication could exist and be valuable under certain conditions, that does not appear to be the case here.

## 10. REDUCED PIPELINE INVESTMENT

76. Dr. Selck describes reduced pipeline investment as an indirect harm to UTC:

In addition to the direct harm to United arising from price erosion, lost unit sales, and lost market share, the reduced revenues from these harms will inhibit United's ability to invest in ongoing development efforts for its pipeline drug candidates and products, which include novel drugs to treat PAH as well as organ manufacturing projects for treating end-stage organ disease.<sup>112</sup>

...

Cash flows from sales of established products is a preferred method for financing development efforts.<sup>113</sup>

77. As I address above, Dr. Selck's opinions about price erosion and lost sales are contradicted by evidence from UTC. In any event, Dr. Selck acknowledges that profits from the sales of existing drugs are not UTC's only possible financing mechanism—he believes they are a “preferred method.”<sup>114</sup> Yet he claims that:

United's research and development efforts would be harmed by reduced revenues of Tyvaso and Tyvaso DPI.<sup>115</sup>

78. What Dr. Selck fails to acknowledge is that, as of December 31, 2023, UTC had \$4.9 billion in cash and marketable securities – an increase of \$749 million in a year.<sup>116</sup> Already deducted from that increased cash are UTC's recorded total R&D expenses of \$408 million in 2023. This is up from \$323

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<sup>111</sup> Selck Declaration, ¶88.

<sup>112</sup> Selck Declaration, ¶92.

<sup>113</sup> Selck Declaration, ¶93.

<sup>114</sup> Selck Declaration, ¶93.

<sup>115</sup> Selck Declaration, ¶94.

<sup>116</sup> UTC 10-K, 2023, p. 61.

Non-Confidential

million in 2022.<sup>117</sup> As a result, UTC could give up over \$500 million per year in cash flow before it would have to look to outside sources of funding for its R&D program.

79. In fact, UTC just announced a share buyback program of up to \$1 billion – indicating that it believes it has more than sufficient cash to fund future R&D.<sup>118</sup> Furthermore, it appears that UTC can readily issue debt to fund any promising research projects as its interest expense in 2023 amounted to \$59.3 million against net income of \$984.8 million.<sup>119</sup>

80. Thus, it does not appear that UTC is in danger of having to curtail its R&D efforts due to competition from Yutrepia.

## 11. REPUTATIONAL HARM

81. Dr. Selck opines that another form of indirect harm for UTC may be reputational:

If a stay is not granted but a subsequent permanent injunction is granted, Yutrepia may be allowed to enter the market and then be forced to withdraw. Subsequent removal of Yutrepia due to the outcome of this litigation may cause external stakeholders to view United negatively for having removed an additional product from the market for PAH and PH-ILD patients.<sup>120</sup>

82. Dr. Selck's allusions to the fact that UTC is listed as a "public benefit corporation" do not appear to support any claim of reputational harm – other than perhaps calling into question UTC's public benefit purpose.<sup>121</sup>

83. Dr. Selck does not consider whether UTC has already suffered the claimed reputational harm by prior lawsuits attempting to keep Yutrepia off the market and by filing the present lawsuit that is attempting to keep "an additional product from the market for PAH and PH-ILD patients."<sup>122</sup> This reputational harm – to the extent it exists – appears to be entirely within UTC's control.

84. Furthermore, Mr. Benkowitz appeared to be confident that UTC's reputation was solid:

Did you say why would Liquidia become the -- I think I believe -- we believe Tyvaso will continue to be the preferred agent for very -- I mean the big one is

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<sup>117</sup> UTC 10-K, 2023, p. 59.

<sup>118</sup> Press Release, United Therapeutics Corp., United Therapeutics Corporation Announces \$1 Billion Accelerated Share Repurchase Program (3/25/2024) (LIQ\_24-1658\_Appeal\_0000392-393), available at <https://ir.unither.com/press-releases/2024/03-25-2024-110046740>.

<sup>119</sup> UTC 10-K, 2023, p. F-6.

<sup>120</sup> Selck Declaration, ¶95.

<sup>121</sup> Selck Declaration, ¶96.

<sup>122</sup> Selck Declaration, ¶95.

Non-Confidential

that we've got 2 years of patient data, thousands of patients on the product. The patients are -- satisfaction level is incredibly high both by the physicians and by the patients. And so they have that experience with our product, which is incredibly helpful.

I think -- we think the convenience of our device as a differentiator. Ours is one (inaudible) per session. Their's 2. Ours doesn't require cleaning. Their's does. We don't have a max label dose. And so we just think, all in all, the patients and the physicians are going to prefer our product. We think the other thing that's attractive about our devices are just what's called a low-flow device and so that means that it requires less patient effort to actually breed the drug.

And then as a result of that, that property or that characteristic. The drug is actually getting deeper into the lungs. So what you see with a high flow device, which is what their device is. So we think all in all, the totality of the characteristics of our device are going to be preferred by physicians and patients.

**And then on the payer side, you were in these discussions right now with payers and kind of working that out. But I think we're feeling increasingly confident that there's not going to be preference, so it's going to be a level playing field. So it's really going to be up to the patient and the physician, and we feel confident about how we're going to do there.**<sup>123</sup>

## **12. IRREPARABILITY**

85. Dr. Selck makes two arguments about the irreparability of any harm should a stay not be granted:

- Difficulty of quantifying the harm<sup>124</sup>
- Liquidia's supposed inability to pay sufficient damages<sup>125</sup>

86. Dr. Selck's reasoning opinion about Liquidia's supposed inability to pay sufficient damages is based on his comparison of an overstated and unsupported estimate of possible damages with Liquidia's stock market capitalization:

To demonstrate Liquidia's likely inability to compensate United for its infringement (even if damages could be calculated), I have prepared an illustrative analysis that estimates an approximate low-end magnitude of lost revenues that United is likely to suffer if Yutrepia enters the market. This analysis assumes the losses stem only from price erosion and lost sales (as discussed in Sections 4.2 and 4.3).

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<sup>123</sup> LIQ\_24-1658\_Appeal\_0000137-146 at 142 [Refinitiv StreetEvents, Edited Transcript, UTHR.0Q - United Therapeutics Corp at TD Cowen Health Care Conference, March 05, 2024, p. 6] (**emphasis added**).

<sup>124</sup> Selck Declaration, §5.2.

<sup>125</sup> Selck Declaration, §5.5.

Non-Confidential

[REDACTED]

In contrast, Liquidia Corporation's market capitalization—a measure of how much the entire company is worth as determined by the stock market—was \$1.054 billion as of April 17, 2024.<sup>126</sup>

87. I do not believe that Dr. Selck's estimate is even "illustrative" as it is contrary to UTC management's own forecasts and is based largely on an inapt analogy.<sup>127</sup> Dr. Selck's estimates explicitly ignore [REDACTED]

[REDACTED].<sup>128</sup> In contrast, Dr. Selck opines that both the number of patients and the price would [REDACTED]<sup>129</sup> Dr. Selck provides no justification for his [REDACTED] figures.

88. At this point in time, I have not estimated damages. However, based on the evidence that UTC is [REDACTED] Dr. Selck's figures are significantly overstated. Furthermore, Dr. Selck has erred in a number of additional ways.

89. First, Dr. Selck's forecasted losses include losses for all of 2024 – which is clearly incorrect as he filed his declaration on April 17, 2024 and there have been no lost sales or price erosion to date.

90. Second, Dr. Selck does nothing to calculate Liquidia's ability to pay beyond referring to Liquidia's stock market value. Dr. Selck does not examine Liquidia's future cash flows from sales of Yutrepia or its ability to raise additional financing. Because UTC has not given any evidence that it is planning to reduce the price of Tyvaso on the launch of Yutrepia, there is no evidence to conclude that Liquidia could not pay any alleged monetary damages. To the extent that some of Liquidia's sales replace UTC's sales, the profits made by Liquidia from the replacement sales should be sufficient to later compensate UTC for its lost profits. In addition, Liquidia will likely make sales that do not replace UTC sales and those profits would also be available to pay a subsequent damages award.

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<sup>126</sup> Selck Declaration, ¶139.

<sup>127</sup> Furthermore, his calculation is based on revenues – not profits. Dr. Selck does not start with UTC's own forecast of prices, nor does he allow any price change past the first year.

<sup>128</sup> UTC\_24-1658\_Appeal\_000101-0109 [United Therapeutics Tyvaso Forecast (2023-2035)].

<sup>129</sup> Selck Declaration, ¶139.

Non-Confidential

91. Dr. Selck's arguments about the difficulty of quantifying damages are largely directed at the "complexity of the marketplace."<sup>130</sup> He claims that:

Due to the complexity of the PAH and PH-ILD marketplaces, it will be infeasible to fully quantify and compensate the harms suffered by United in the absence of a stay.<sup>131</sup>

...

The PAH market is relatively more established, with nebulized Tyvaso obtaining FDA approval in 2009 and multiple other treatment options available for treatment of PAH.<sup>132</sup>

...

The PH-ILD market is complex and unique because it is essentially a new market.<sup>133</sup>

92. Thus, Dr. Selck is opining that damages are difficult to quantify for both existing markets with multiple competitors and new markets with a limited number of competitors.

93. Dr. Selck does not point to any evidence that the "PAH market" is any more complex than other markets for pharmaceutical products for which damages have been calculated.

94. In my opinion, damages could be quantified in this case. Dr. Selck has apparently never given an opinion quantifying damages in a U.S. patent litigation.<sup>134</sup> I have been quantifying damages from patent infringement for over 25 years and there is nothing in this case that appears to be so unique as to preclude a proper estimate of damages.

95. In summary, Dr. Selck's "illustrative" calculation of the possible damages in this case are inflated and directly contradicted by UTC's own forecasts of [REDACTED]. In my opinion, there is nothing about this case that would preclude a calculation of damages.

### **13. BALANCE OF EQUITIES**

96. Dr. Selck also claims that the harm to UTC is disproportionate to the gain to Liquidia.<sup>135</sup> This opinion is based on a theoretical construct that ignores the actual evidence in the case. Dr. Selck provides a rough calculation based on assumptions that 1) Yutrepia's launch will significantly erode UTC's price

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<sup>130</sup> Selck Declaration, §5.2.

<sup>131</sup> Selck Declaration, ¶99.

<sup>132</sup> Selck Declaration, ¶101.

<sup>133</sup> Selck Declaration, ¶102.

<sup>134</sup> Selck Declaration, Attachment A-1.

<sup>135</sup> Selck Declaration, §5.4.

Non-Confidential

for Tyvaso; and 2) that every patient taking Yutrepia would have otherwise been taking Tyvaso. UTC's own management statements and forecast contradict both of these assumptions.<sup>136</sup>

97. Dr. Selck further claims that:

United's investments in the Tyvaso products and in developing the PH-ILD market exceed Liquidia's investments. The harms to United if a stay is not granted exceed the harms that Liquidia may suffer if the stay is granted.<sup>137</sup>

98. These first sentence above ("United's investments") and the second sentence above ("harms to United ... exceed harms [to] Liquidia") are unrelated. There is no sense in which the relative investments by UTC and Liquidia indicate any balance of equities or potential harms. Historic R&D expenditures by both companies are sunk costs and are not going to be affected by a stay.

99. Dr. Selck then claims that:

By relying on Tyvaso as the reference product for Yutrepia to earn approval, Liquidia is freeriding on United's efforts to bring the Tyvaso products to market without incurring the significant costs that United had to spend and risks that United had to take on the development and commercialization of the Tyvaso products.

...

If Yutrepia is not prevented from entry, United will be harmed by losing the ability to recoup its significant research and development expenses and earn the rewards it should be able to earn from successfully taking the risk to develop the first drug in a new indication. Conversely, if Yutrepia is prevented from launching Yutrepia, any lost investments into drug development that Liquidia will incur will be small compared to what United will experience; Liquidia currently does not have any clinical study results available for PH-ILD.<sup>138</sup>

100. As an initial matter, Dr. Selck's use of the term "freeriding" is pejorative. It is also described as one of the advantages of being second to market.<sup>139</sup> Dr. Selck has not identified anything, nor am I aware of anything, that Liquidia has done that could be considered illegal or unethical in choosing to get a product approved through a 505(b)(2) process.<sup>140</sup>

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<sup>136</sup> Section 6.

<sup>137</sup> Selck Declaration, ¶141.

<sup>138</sup> Selck Declaration, ¶144.

<sup>139</sup> Lieberman, Marvin B. and David B. Montgomery, "First-Mover Advantages," *Strategic Management Journal* 9, (1988): 41–58, at 41.

<sup>140</sup> Selck Declaration, ¶27.

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101. Dr. Selck's opinion about the balance of equities is derivative of his other opinions about price erosion, lost sales and the difficulty of calculating damages. He assumes significant price erosion and lost sales and then opines on the balance of equities.

102. Dr. Selck performs a simple comparison of the R&D expenditures of UTC and Liquidia to assert an imbalance. However, as I am sure Dr. Selck is aware, the entirety of UTC's R&D expenditures to obtain approval for Tyvaso are not at risk. First, UTC has been selling Tyvaso since 2009 and has almost certainly recouped its initial investment by now. In 2022 and 2023 alone, UTC sold a total of \$889 million of Tyvaso DPI.<sup>141</sup> Second, UTC has likely recouped at least some of its investments in the PH-ILD indication through its sales of Tyvaso with a PH-ILD indication since April of 2021. Third, any lost sales or price erosion due to Yutrepia's launch would reduce UTC's profits — not eliminate them. Thus, a more accurate way to characterize UTC's risk is that it might get a lower return on its investment than it otherwise would. This reduced return is equal to any lost profits damages UTC might suffer — so this discussion collapses into the prior discussions about price erosion and lost sales.

103. Dr. Selck does not address the more typical question when considering the balance of equities — the relative effects of a stay on Liquidia compared to UTC.

104. A stay in this case would continue to allow UTC to generate profits from the sale of Tyvaso. I do not have any opinion at the moment as to how much difference a stay would make to UTC — *i.e.* how different UTC's profits would be with and without a stay — and Dr. Selck does not provide this analysis either. As discussed previously, at the end of 2023 UTC had \$4.9 billion in cash and marketable securities — an increase of \$749 million in a year.<sup>142</sup> In contrast, UTC recorded total R&D expenses of \$408 million in 2023 up from \$323 million in 2022.<sup>143</sup> Furthermore, UTC reported net income for 2023 of \$984.8 million (42.3% of sales) up from \$727.3 million in 2022 and \$475.8 million in 2021.<sup>144</sup> Thus, UTC is a very profitable company and its 2023 forecast evidences UTC's [REDACTED]

105. The harm to Liquidia from a stay is significant as it would delay the receipt of potentially significant revenues and profits to a company that is currently losing money.<sup>145</sup> Liquidia's financial position is less secure than UTC's so the loss of a dollar of profits to Liquidia is going to matter more to it

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<sup>141</sup> UTC 10-K, 2023, p. 56.

<sup>142</sup> UTC 10-K, 2023, p. 61.

<sup>143</sup> UTC 10-K, 2023, p. 59.

<sup>144</sup> UTC 10-K, 2023, F-6.

<sup>145</sup> Liquidia 10-K, 2023, p. F-5.

Non-Confidential

than the loss of a dollar of profits to UTC. In 2023 Liquidia reported revenue of \$17.5 million and a net loss of \$78.5 million.<sup>146</sup> At the end of 2023, Liquidia reported \$83.7 million in the bank against total cash spent on operations in the 2023 of \$41.6 million.<sup>147</sup>

106. The balance of equities in this case, from a financial perspective, rests on an opinion about the relative incremental profits and losses to UTC and Liquidia from launching Yutrepia. UTC's management is not forecasting any loss of sales or profits from Yutrepia's launch. On the other hand, Liquidia's lead product is Yutrepia – staying its launch will have a substantial effect on Liquidia.<sup>148</sup> In this case, the balance of equities favors Liquidia.

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<sup>146</sup> Liquidia 10-K, 2023, p. 81.

<sup>147</sup> Liquidia 10-K, 2023, p. F-4, F-7.

<sup>148</sup> Liquidia 10-K, 2023, p. 4.



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**14. SIGNATURE PAGE**

107. I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

A handwritten signature in blue ink, appearing to read 'DK', is written above a horizontal line.

Douglas G. Kidder

April 26, 2024

**Douglas G. Kidder**

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 dkidder@oskr.com

**CURRENT EMPLOYMENT**

2008 - Present      **Managing Partner**      **OSKR, LLC**      **Emeryville, CA**  
 Patent valuation and business strategy expert with over 25 years of experience analyzing patents, business opportunities and risks. Consult for clients on complex damages and licensing issues with a particular focus on technology companies. [www.oskr.com](http://www.oskr.com)

**PRIOR EXPERIENCE**

2014 – 2020      **Adjunct Professor**      **Golden Gate University**      **San Francisco, CA**  
 Taught a graduate-level course in the School of Accounting on damages.

2001 – 2007      **Principal**      **LECG, LLC**      **Emeryville, CA**

1997 – 1999      Primarily consulted for companies on damages issues arising from allegations of antitrust and intellectual property infringement.

2005      **Office Director**  
 Responsible for the operations of a 90-person office including reviews, hiring, firing, promotions, morale and general administration.

2001 - 2005      **Special Assistant to the Chairman, Strategy**  
 Advised the Chairman on corporate acquisitions and general strategic direction.

2000 - 2001      **Managing Director**      **SCIENT**      **San Francisco, CA**  
 Joined corporate strategy group to help design and implement a turn-around for this Internet consulting firm. Responsible for company organizational transition.

1999 - 2000      **VP Operations**      **KENAMEA**      **San Francisco, CA**  
 Helped develop strategy and business plan for an Internet software startup. Managed the operations of the company as we grew from 4 to 25 people.

1996 - 1997      **Principal**      **MANAGEMENT RESOURCES**      **Berkeley, CA**  
 Independent consultant performing due diligence and analyses of startup high-tech business opportunities.

1995 – 1996      **Vice President**      **WALT DISNEY**      **Glendale, CA**  
**Business Development**      **IMAGINEERING**  
 Evaluated new business ideas for WDI including creative concepts and technology initiatives.

1993 - 1995      **Director**      **VALSPAR**      **Chicago, IL**  
 Managed the production planning, distribution and I/T functions for the \$200 million Consumer Paint Division.

1992-1993      **Senior Associate**      **BOOZ, ALLEN**      **San Francisco, CA**  
 1990-1991      **Associate**  
 1987-1989      **Analyst**

Performed general business strategy and organization assignments across a wide range of industries. Exceptional (second in the history of the firm) promotion granted from Analyst to Associate waiving the usual requirement for an MBA.

1984 - 1986	<b>Lecturer</b>	<b>UC BERKELEY</b>	<b>Berkeley, CA</b>
	Taught an introductory computer science class.		
1986	<b>Chief Engineer</b>	<b>WINDWARD YACHTS</b>	<b>Oakland, CA</b>
	Responsible for the detailed design of custom yachts.		

#### **OTHER BUSINESS EXPERIENCE**

2013 – Present	<b>Naval Architect</b>		<b>Berkeley, CA</b>
	Design custom rowing shells for open water.		
2001 - 2013	<b>President</b>	<b>MAAS BOAT COMPANY</b>	<b>Richmond, CA</b>
	Purchased, managed and sold a company that manufactures and sells open water rowing shells in the U.S. and around the world. Primary responsibilities were design, management, marketing, finance, and license negotiation.		
2008 – 2012	<b>President</b>	<b>NAOWRC, Inc.</b>	<b>Richmond, CA</b>
	Created a national championship for open water rowing that brought together rowers from around the U.S. and the world.		
2004 – 2011	<b>President</b>	<b>KIDDER RACING</b>	<b>Richmond, CA</b>
	Developed design brief for an innovative one-person sailing skiff. Founded company and was responsible for final design, strategy, marketing and finance.		

#### **Board Positions**

Skyflow Inc. (former), NextWindow (former), Hero Arts (Advisory Board, former), Trade New Zealand (Advisory Board, former), Berkeley Rowing Club (former)

#### **Other**

Member of the Licensing Executives Society  
 Member of the National Associate of Business Economists  
 Member of The Sedona Conference  
 Participant in the Stanford IP Roundtable  
 Booz, Allen & Hamilton Professional Excellence Award  
 Outstanding Graduate Student Instructor Award  
 Significant experience evaluating new businesses.

#### **EDUCATION**

1986	M.Sc., University of California at Berkeley
1983	B.A. with Honors, Amherst College
	Elected to Sigma Xi, National Scientific Honor Society

#### **PUBLICATIONS & PRESENTATIONS**

“Are Patents Really Options?”, *les Nouvelles Journal of the Licensing Executives Society*, V. 38(4), December 2003.

“Most Favored Licensee Clauses: Draining the Swamp” presentation at *Advanced Topics in IP Valuation* to the Intellectual Property Society, July 2004.

“Reasonable Royalties by the New Rules”, *Dunn on Damages*, Summer 2011.

“Infringer’s Profits Should Not Be the Focus of Patent Damages Cases”, *Dunn on Damages*, Fall 2011.

“Simply Wrong: The 25% Rule Examined”, *les Nouvelles Journal of the Licensing Executives Society*, December, 2011.

“For Want of Damages the Case was Tossed: Judge Posner’s Ruling in Apple v. Motorola”, *Dunn on Damages*, Fall 2012.

“Nash Bargaining and Patent Damages”, *les Nouvelles Journal of the Licensing Executives Society*, March 2014.

“Lump Sums, Running Royalties and Real Options”, *les Nouvelles Journal of the Licensing Executives Society*, December 2015.

### **Litigation Experience**

Ossur Holdings Inc. and Generation II USA, Inc., v. Bellacure, Inc., Shane Sterling and Maurice Cannon. Before United States District Court, Western District of Washington at Seattle. Civil Action No: 05-CV-01552-CMP. Retained by counsel for plaintiffs, re: lost profits and unjust enrichment due to alleged theft of trade secrets in the medical device industry (osteoarthritis knee braces).

Google, Inc. v. American Blind & Wallpaper Factory, Inc. Before United States District Court, Northern District of California. Case No. C 03-5340 JF EAI. Retained by counsel for plaintiffs re: damages arising from Google's alleged infringement of American Blind & Wallpaper's trademarks.

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Oncology Tech, LLC v. Elekta AB and Elekta, Inc. Before United States District Court, Western District of Texas, San Antonio Division. Case No: 5:12-CV-00314-HLH. Retained by counsel for defendants re: damages arising from alleged breach of contract.

American Medical Response, Inc. v. Paramedics Plus, LLC. Before Superior Court of the State of California, County of Alameda. Case No: RG10541623. Retained by counsel for defendant re: damages arising from alleged low-cost bid for emergency medical services.

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Silicon Storage Technology, Inc. v. National Union Fire Insurance Company of Pittsburgh, PA and XL Specialty Insurance Company. Before United States District Court, Northern District of California. Case No: 5:13-CV-05658. Retained by counsel for defendants re: damages arising from a claim for theft of trade secrets.

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Hughes & Company Construction, Inc. v. Weber Hung Family Trust. Before American Arbitration Association. Case No. 01-20-0004-8744. Retained by counsel for defendants / counterclaimants re: damages from breach of contract.

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RSB Spine, LLC v. Medacta USA, Inc. Before United States District Court, District of Delaware, C.A. No. 18-1973-RGA. Retained by counsel for RSB Spine re: damages from patent infringement.

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Insulet Corporation v. EOFlow Ltd., EOFlow, Inc., Flex Ltd., Flextronics Corporation, Flextronics Medical Sales and Marketing Ltd., Luis J. Malave, Steven Dilanni, and Ian Welsford. Before United States District Court for the District of Massachusetts. Case No. 1:23-cv-11780. Retained by counsel for defendants irreparable harm in the context of a motion for preliminary injunction.

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Sectra Communications AB v. Absolute Software Inc. and NetMotion Software, Inc. Before United States District Court for the Western District of Washington at Seattle. Case No. 2:22-cv-0353-RSM. Retained by counsel for defendants and counterclaimants re: damages from patent infringement.

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International Business Machines Corporation v. Zynga, Inc. Before United States District Court for the District of Delaware. Case No. 22-590-GBW. Retained by counsel for defendants re: damages from patent infringement.

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**Documents Considered**

**Legal Filings**

Amended Final Judgement, March 28, 2024  
Final Judgement, September 9, 2022  
Memorandum Order Granting Post-Judgement Relief, March 28, 2024  
Plaintiff's Motion for Stay Pending Appeal, April 18, 2024

**Declarations**

Declaration of Fredric Selck, Ph.D. in Support of Motion to Stay, April 17, 2024

**Patents**

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**Correspondence**

Letter from Liquidia Technologies, Inc. to United Therapeutics Corporation Re: "Notification Pursuant to § 505(b)(3)(B) of the Federal Food, Drug, & Cosmetic Act (21 U.S.C. § 355(b)(3)(B)(i)) and 21 C.F.R. §314.52)", July 24, 2023

**Public Financial Documents**

Liquidia Corporation Form 10-K for the year ending December 31, 2022  
Liquidia Corporation Form 10-K for the year ending December 31, 2023  
Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023  
Refinitiv Edited Transcript UTHR.0Q - Q2 2023 United Therapeutics Corp Earnings Call, August 2, 2023  
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Refinitiv StreetEvents, Edited Transcript, UTHR.0Q - United Therapeutics Corp at TD Cowen Health Care Conference, March 05, 2024  
United Therapeutics Corporation Form 10-K for the year ended December 31, 2022  
United Therapeutics Corporation Form 10-K for the year ended December 31, 2023

**Bates-Stamped Documents**

UTC\_24-1658\_Appeal\_000001-0100  
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**Third Party**

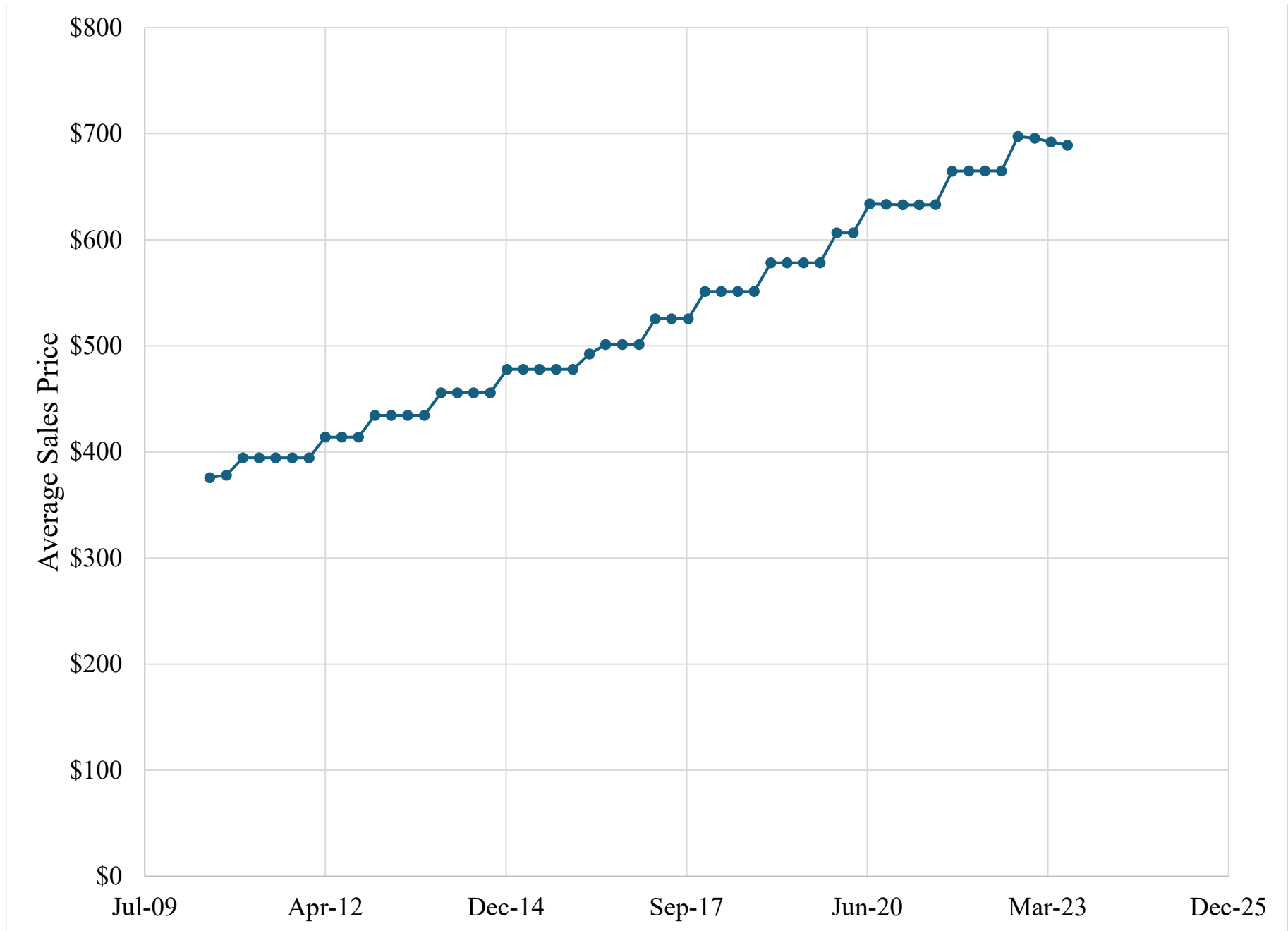
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<https://www.cms.gov/medicare/payment/part-b-drugs>  
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<https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-K/section-414.904>  
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[https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555\\_23-\\_\\_\\_\\_PetitionForAWritOfCertiorari.pdf](https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-____PetitionForAWritOfCertiorari.pdf)

**Tyvaso Average Sales Price per 1.74-MG Dose**



**Tyvaso Price Growth**

<b>Quarter</b>	<b>ASP</b>
2010q3	\$375.78
2023q3	\$688.98
CAGR	4.77%

*Source:*  
*Exhibit 3.3*

## Exhibit 3.3

## Tyvaso Average Sale Price Data

HCPCS				Payment Limit	ASP Quarter		
Code	Labeler Name	Drug Name	Short Description	Effective Date [1]	Start Date [2]	Dosage	ASP [3]
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2011	7/1/2010	1.74 MG	\$ 375.78
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2011	10/1/2010	1.74 MG	\$ 378.09
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2011	1/1/2011	1.74 MG	\$ 394.48
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2011	4/1/2011	1.74 MG	\$ 394.50
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2012	7/1/2011	1.74 MG	\$ 394.48
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2012	10/1/2011	1.74 MG	\$ 394.48
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2012	1/1/2012	1.74 MG	\$ 394.49
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2012	4/1/2012	1.74 MG	\$ 414.09
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2013	7/1/2012	1.74 MG	\$ 414.08
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2013	10/1/2012	1.74 MG	\$ 414.07
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2013	1/1/2013	1.74 MG	\$ 434.38
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2013	4/1/2013	1.74 MG	\$ 434.39
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2014	7/1/2013	1.74 MG	\$ 434.37
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2014	10/1/2013	1.74 MG	\$ 434.37
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2014	1/1/2014	1.74 MG	\$ 455.65
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2014	4/1/2014	1.74 MG	\$ 455.66
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2015	7/1/2014	1.74 MG	\$ 455.65
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2015	10/1/2014	1.74 MG	\$ 455.65
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2015	1/1/2015	1.74 MG	\$ 477.77
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2015	4/1/2015	1.74 MG	\$ 477.77
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2016	7/1/2015	1.74 MG	\$ 477.77
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2016	10/1/2015	1.74 MG	\$ 477.77
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2016	1/1/2016	1.74 MG	\$ 477.77
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2016	4/1/2016	1.74 MG	\$ 492.34
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2017	7/1/2016	1.74 MG	\$ 501.22
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2017	10/1/2016	1.74 MG	\$ 501.22
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2017	1/1/2017	1.74 MG	\$ 501.21
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2017	4/1/2017	1.74 MG	\$ 525.55
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2018	7/1/2017	1.74 MG	\$ 525.55
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2018	10/1/2017	1.74 MG	\$ 525.53
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2018	1/1/2018	1.74 MG	\$ 551.25
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2018	4/1/2018	1.74 MG	\$ 551.25
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2019	7/1/2018	1.74 MG	\$ 551.25

## Exhibit 3.3

## Tyvaso Average Sale Price Data

HCPCS				Payment Limit	ASP Quarter		
Code	Labeler Name	Drug Name	Short Description	Effective Date [1]	Start Date [2]	Dosage	ASP [3]
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2019	10/1/2018	1.74 MG	\$ 551.25
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2019	1/1/2019	1.74 MG	\$ 578.26
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2019	4/1/2019	1.74 MG	\$ 578.26
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2020	7/1/2019	1.74 MG	\$ 578.26
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2020	10/1/2019	1.74 MG	\$ 578.26
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2020	1/1/2020	1.74 MG	\$ 606.60
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2020	4/1/2020	1.74 MG	\$ 606.60
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2021	7/1/2020	1.74 MG	\$ 633.81
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2021	10/1/2020	1.74 MG	\$ 633.31
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2021	1/1/2021	1.74 MG	\$ 632.92
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2021	4/1/2021	1.74 MG	\$ 632.97
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2022	7/1/2021	1.74 MG	\$ 633.09
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2022	10/1/2021	1.74 MG	\$ 664.51
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2022	1/1/2022	1.74 MG	\$ 664.75
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2022	4/1/2022	1.74 MG	\$ 664.76
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2023	7/1/2022	1.74 MG	\$ 664.76
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	4/1/2023	10/1/2022	1.74 MG	\$ 697.31
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	7/1/2023	1/1/2023	1.74 MG	\$ 695.64
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	10/1/2023	4/1/2023	1.74 MG	\$ 692.11
J7686	UNITED THERAPEUTICS	TYVASO	Treprostinil, non-comp unit	1/1/2024	7/1/2023	1.74 MG	\$ 688.98

## Source:

CMS ASP Pricing Files, accessed at <https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files>

## Notes:

[1] Date on which rates based on the indicated ASP become effective. CMS ASP Pricing Files indicate that payment limits are based on ASP data from two quarters prior.

[2] First day of the quarter the indicated ASP data was collected.

[3] CMS ASP Pricing Files report payment allowance limits. These limits are calculated as 106% of ASP. Therefore ASP is calculated as (1/1.06) times the payment limit. See <https://www.cms.gov/medicare/payment/part-b-drugs>; <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-K/section-414.904>.

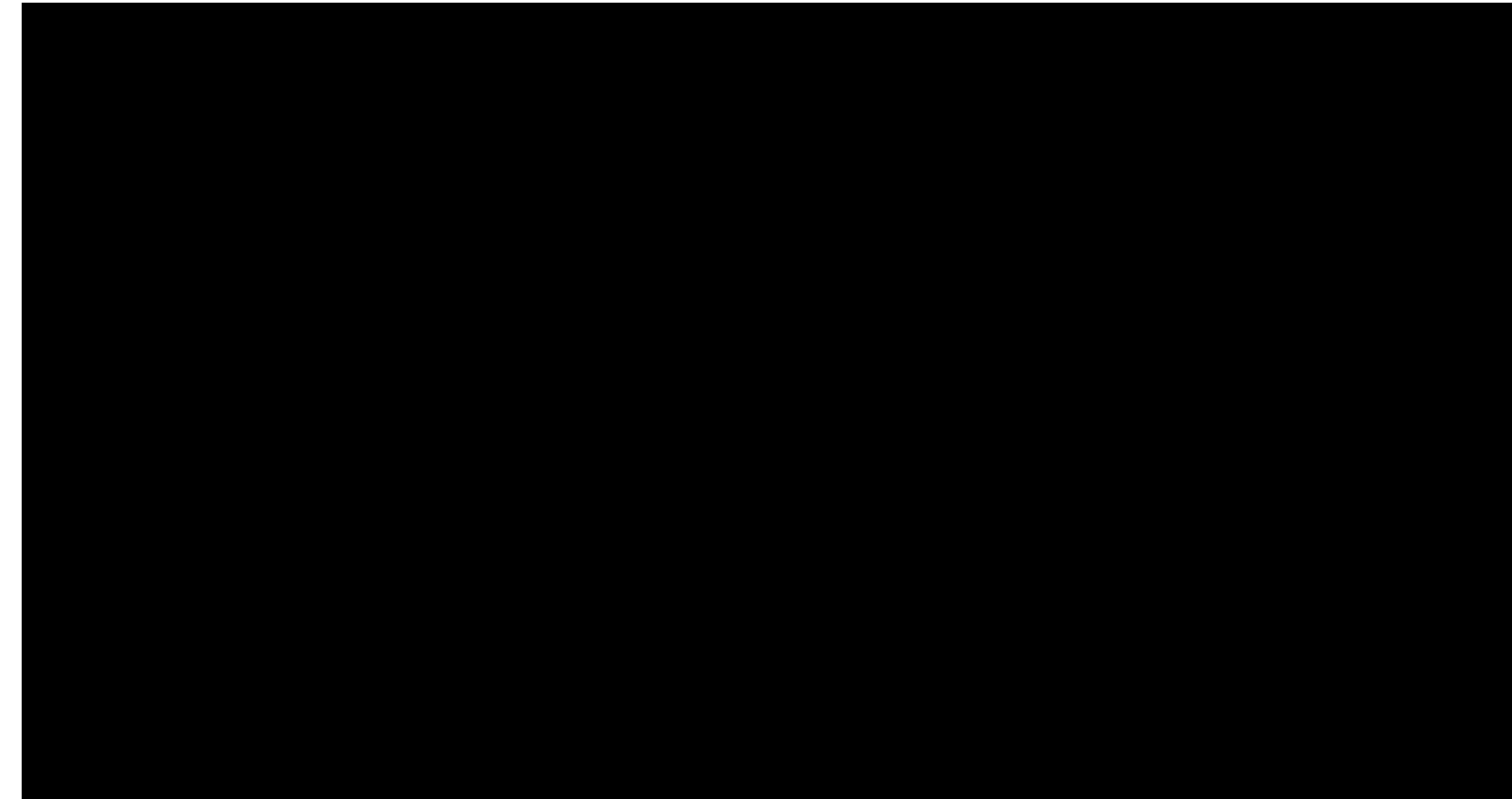
### Annual Price for Therapy (Forecast)

UTC\_PH-ILD\_009410 – 18 [UTHR Forecast 2023-2035 09-06-2023]

**CONFIDENTIAL MATERIAL OMITTED**

**Exhibit 4.2**

**UTC Forecasted Tyvaso Patients**



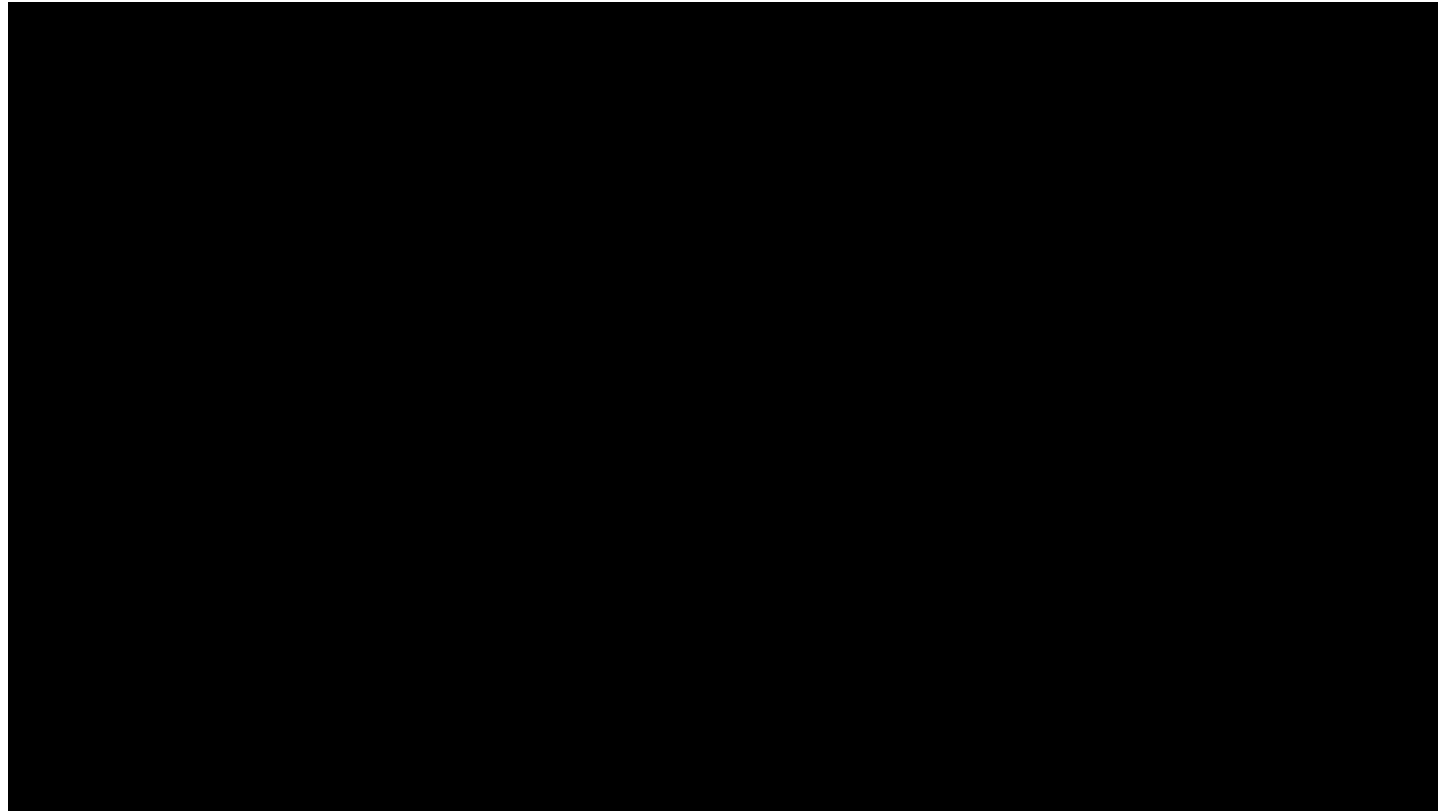
*Source:*

*UTC\_PH-ILD\_009410 – 18 [UTHR Forecast 2023-2035 09-06-2023]*

CONFIDENTIAL MATERIAL OMITTED

Exhibit 4.3

UTC Forecasted Revenues from Tyvaso



Source:

UTC\_PH-ILD\_009410 – 18 [UTHR Forecast 2023-2035 09-06-2023]



## Stock Price Changes on Major Dates

Date	Event	Price Change		Price Change is Outlier		Additional Sources
		LQDA	UTHR	LQDA	UTHR	
31-Mar-2021	Tyvaso (nebulized) receives FDA approval for PH-ILD indication	5.9%	1.1%	No	No	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/022387Orig1s017.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/022387Orig1s017.pdf</a>
01-Apr-2021	UTC announces Tyvaso FDA approval for PH-ILD	2.6%	15.0%	No	Yes	<a href="https://pipeline.unither.com/wp-content/uploads/2021/05/2021-04-01-INCREASE-approval-FINAL-formatted.pdf">https://pipeline.unither.com/wp-content/uploads/2021/05/2021-04-01-INCREASE-approval-FINAL-formatted.pdf</a>
05-Nov-2021	Yutrepia receives tentative FDA approval for PAH indication	-4.2%	0.4%	No	No	<a href="https://www.liquidia.com/products-and-pipeline/overview">https://www.liquidia.com/products-and-pipeline/overview</a>
08-Nov-2021	Liquidia announces tentative FDA approval for PAH indication	4.1%	-0.1%	No	No	<a href="https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil">https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil</a>
23-May-2022	Tyvaso DPI receives FDA approval	-18.8%	11.6%	Yes	Yes	<a href="https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/214324Orig1s000ltr.pdf">https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2022/214324Orig1s000ltr.pdf</a>
24-May-2022	UTC announces Tyvaso DPI FDA approval	-28.3%	4.2%	Yes	Yes	<a href="https://ir.unither.com/~media/Files/U/United-Therapeutics-IR/documents/press-releases/2022/2022-05-24-DPI-approval-FINAL-formatted.pdf">https://ir.unither.com/~media/Files/U/United-Therapeutics-IR/documents/press-releases/2022/2022-05-24-DPI-approval-FINAL-formatted.pdf</a>
19-Jul-2022	PATB issues decision finding all claims of '793 Patent unpatentable	45.3%	-1.1%	Yes	No	<a href="https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023_2161663.pdf">https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023_2161663.pdf</a>
30-Aug-2022	Judge denies stay of decision on '793 Patent pending PTAB appeal	-30.4%	0.7%	Yes	No	<a href="https://www.courtlistener.com/docket/17225404/432/united-therapeutics-corporation-v-liquidia-technologies-inc/">https://www.courtlistener.com/docket/17225404/432/united-therapeutics-corporation-v-liquidia-technologies-inc/</a>
31-Aug-2022	Court ruling against '793 Patent	7.2%	3.5%	No	No	<a href="https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-____PetitionForAWritOfCertiorari.pdf">https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-____PetitionForAWritOfCertiorari.pdf</a>
01-Sep-2022	Liquidia shareholder call regarding ruling on '793 Patent	-15.8%	-0.2%	Yes	No	<a href="https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-hatch-waxman-litigation-and-host-call">https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-hatch-waxman-litigation-and-host-call</a>
20-Dec-2023	Federal Circuit affirms PTAB decision to invalidate '793 Patent	35.7%	-6.1%	Yes	Yes	Selek Declaration, ¶61

Source:

Thompson Reuters Eikon Stock Price Data

Note:

Price changes are considered outliers where the normalized change in stock price (difference between % daily change in closing price of stock and % change in closing price of NASDAQ 100 index) deviates by more than two standard deviations from the mean for the period from July 1, 2019 through March 8, 2024.

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
01-Jul-2019	7.96	82.05	7768.138							
02-Jul-2019	7.81	82.75	7799.824	-1.9%	0.9%	0.4%	-2.3%	0.4%	0	0
03-Jul-2019	7.94	81.91	7857.69	1.7%	-1.0%	0.7%	0.9%	-1.8%	0	0
05-Jul-2019	8.24	80.01	7841.301	3.8%	-2.3%	-0.2%	4.0%	-2.1%	0	0
08-Jul-2019	8.23	78.11	7785.787	-0.1%	-2.4%	-0.7%	0.6%	-1.7%	0	0
09-Jul-2019	7.99	80.06	7826.858	-2.9%	2.5%	0.5%	-3.4%	2.0%	0	0
10-Jul-2019	8	79.13	7903.401	0.1%	-1.2%	1.0%	-0.9%	-2.1%	0	0
11-Jul-2019	7.94	77.49	7896.776	-0.7%	-2.1%	-0.1%	-0.7%	-2.0%	0	0
12-Jul-2019	7.86	76.48	7943.241	-1.0%	-1.3%	0.6%	-1.6%	-1.9%	0	0
15-Jul-2019	7.85	76.18	7966.926	-0.1%	-0.4%	0.3%	-0.4%	-0.7%	0	0
16-Jul-2019	7.53	75.92	7927.077	-4.1%	-0.3%	-0.5%	-3.6%	0.2%	0	0
17-Jul-2019	7.71	76.13	7888.762	2.4%	0.3%	-0.5%	2.9%	0.8%	0	0
18-Jul-2019	7.73	76.25	7904.132	0.3%	0.2%	0.2%	0.1%	0.0%	0	0
19-Jul-2019	7.75	75.32	7834.897	0.3%	-1.2%	-0.9%	1.1%	-0.3%	0	0
22-Jul-2019	7.8	74.85	7905.119	0.6%	-0.6%	0.9%	-0.3%	-1.5%	0	0
23-Jul-2019	7.65	74.94	7954.564	-1.9%	0.1%	0.6%	-2.5%	-0.5%	0	0
24-Jul-2019	7.45	76.71	8010.605	-2.6%	2.4%	0.7%	-3.3%	1.7%	0	0
25-Jul-2019	7.42	76.88	7929.867	-0.4%	0.2%	-1.0%	0.6%	1.2%	0	0
26-Jul-2019	7.36	77.6	8016.953	-0.8%	0.9%	1.1%	-1.9%	-0.2%	0	0
29-Jul-2019	7.39	78.2	7989.082	0.4%	0.8%	-0.3%	0.8%	1.1%	0	0
30-Jul-2019	7.43	79.53	7952.473	0.5%	1.7%	-0.5%	1.0%	2.2%	0	0
31-Jul-2019	7.31	79.24	7848.78	-1.6%	-0.4%	-1.3%	-0.3%	0.9%	0	0
01-Aug-2019	6.8	83.07	7801.146	-7.0%	4.8%	-0.6%	-6.4%	5.4%	0	1
02-Aug-2019	6.35	83.26	7692.801	-6.6%	0.2%	-1.4%	-5.2%	1.6%	0	0
05-Aug-2019	5.91	79.11	7415.691	-6.9%	-5.0%	-3.6%	-3.3%	-1.4%	0	0
06-Aug-2019	6.76	78.38	7521.322	14.4%	-0.9%	1.4%	13.0%	-2.3%	1	0
07-Aug-2019	6.67	79.89	7551.9	-1.3%	1.9%	0.4%	-1.7%	1.5%	0	0
08-Aug-2019	7.31	81.67	7724.83	9.6%	2.2%	2.3%	7.3%	-0.1%	0	0
09-Aug-2019	7.1	81.6	7646.268	-2.9%	-0.1%	-1.0%	-1.9%	0.9%	0	0
12-Aug-2019	6.94	81.19	7561.682	-2.3%	-0.5%	-1.1%	-1.1%	0.6%	0	0
13-Aug-2019	6.62	80.16	7728.151	-4.6%	-1.3%	2.2%	-6.8%	-3.5%	0	0
14-Aug-2019	6.12	79.32	7490.13	-7.6%	-1.0%	-3.1%	-4.5%	2.0%	0	0
15-Aug-2019	6.29	79.52	7484.888	2.8%	0.3%	-0.1%	2.8%	0.3%	0	0
16-Aug-2019	5.99	81.37	7604.109	-4.8%	2.3%	1.6%	-6.4%	0.7%	0	0
19-Aug-2019	5.65	81.82	7719.323	-5.7%	0.6%	1.5%	-7.2%	-1.0%	0	0
20-Aug-2019	5.47	81.31	7664.471	-3.2%	-0.6%	-0.7%	-2.5%	0.1%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
21-Aug-2019	5.59	82.78	7733.216	2.2%	1.8%	0.9%	1.3%	0.9%	0	0
22-Aug-2019	5.66	82.85	7707.427	1.3%	0.1%	-0.3%	1.6%	0.4%	0	0
23-Aug-2019	5.17	80.71	7464.995	-8.7%	-2.6%	-3.1%	-5.5%	0.6%	0	0
26-Aug-2019	5.52	81.5	7575.019	6.8%	1.0%	1.5%	5.3%	-0.5%	0	0
27-Aug-2019	4.55	80.01	7566.027	-17.6%	-1.8%	-0.1%	-17.5%	-1.7%	1	0
28-Aug-2019	4.69	81.05	7587.896	3.1%	1.3%	0.3%	2.8%	1.0%	0	0
29-Aug-2019	4.52	82.73	7702.312	-3.6%	2.1%	1.5%	-5.1%	0.6%	0	0
30-Aug-2019	4.06	82.56	7690.998	-10.2%	-0.2%	-0.1%	-10.0%	-0.1%	0	0
03-Sep-2019	3.29	81.025	7609.513	-19.0%	-1.9%	-1.1%	-17.9%	-0.8%	1	0
04-Sep-2019	3.39	80.81	7719.246	3.0%	-0.3%	1.4%	1.6%	-1.7%	0	0
05-Sep-2019	3.88	81.05	7862.539	14.5%	0.3%	1.9%	12.6%	-1.6%	1	0
06-Sep-2019	3.96	80.44	7852.539	2.1%	-0.8%	-0.1%	2.2%	-0.6%	0	0
09-Sep-2019	3.86	80.1	7832.403	-2.5%	-0.4%	-0.3%	-2.3%	-0.2%	0	0
10-Sep-2019	4.15	81.83	7814.742	7.5%	2.2%	-0.2%	7.7%	2.4%	0	0
11-Sep-2019	4.22	82.92	7887.581	1.7%	1.3%	0.9%	0.8%	0.4%	0	0
12-Sep-2019	4.13	79.82	7917.34	-2.1%	-3.7%	0.4%	-2.5%	-4.1%	0	0
13-Sep-2019	4.05	80.69	7892.955	-1.9%	1.1%	-0.3%	-1.6%	1.4%	0	0
16-Sep-2019	4.11	83.53	7852.412	1.5%	3.5%	-0.5%	2.0%	4.0%	0	0
17-Sep-2019	4	85.87	7888.786	-2.7%	2.8%	0.5%	-3.1%	2.3%	0	0
18-Sep-2019	4.08	84.2	7888.556	2.0%	-1.9%	0.0%	2.0%	-1.9%	0	0
19-Sep-2019	4	85.92	7901.792	-2.0%	2.0%	0.2%	-2.1%	1.9%	0	0
20-Sep-2019	4.01	85.99	7823.553	0.2%	0.1%	-1.0%	1.2%	1.1%	0	0
23-Sep-2019	4.04	85.08	7818.61	0.7%	-1.1%	-0.1%	0.8%	-1.0%	0	0
24-Sep-2019	3.99	85.43	7710.044	-1.2%	0.4%	-1.4%	0.2%	1.8%	0	0
25-Sep-2019	3.97	85	7803.541	-0.5%	-0.5%	1.2%	-1.7%	-1.7%	0	0
26-Sep-2019	3.78	82.2	7771.992	-4.8%	-3.3%	-0.4%	-4.4%	-2.9%	0	0
27-Sep-2019	3.84	80.84	7681.579	1.6%	-1.7%	-1.2%	2.8%	-0.5%	0	0
30-Sep-2019	3.56	79.75	7749.449	-7.3%	-1.3%	0.9%	-8.2%	-2.2%	0	0
01-Oct-2019	3.53	78.36	7684.142	-0.8%	-1.7%	-0.8%	0.0%	-0.9%	0	0
02-Oct-2019	3.69	79.42	7550.786	4.5%	1.4%	-1.7%	6.3%	3.1%	0	0
03-Oct-2019	3.59	78.31	7638.395	-2.7%	-1.4%	1.2%	-3.9%	-2.6%	0	0
04-Oct-2019	3.65	79.19	7754.102	1.7%	1.1%	1.5%	0.2%	-0.4%	0	0
07-Oct-2019	3.96	79.95	7725.129	8.5%	1.0%	-0.4%	8.9%	1.3%	0	0
08-Oct-2019	3.96	78.71	7604.27	0.0%	-1.6%	-1.6%	1.6%	0.0%	0	0
09-Oct-2019	3.83	79.71	7690.529	-3.3%	1.3%	1.1%	-4.4%	0.1%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
10-Oct-2019	3.99	80.75	7740.362	4.2%	1.3%	0.6%	3.5%	0.7%	0	0
11-Oct-2019	4.05	81.89	7843.875	1.5%	1.4%	1.3%	0.2%	0.1%	0	0
14-Oct-2019	3.98	81.25	7842.334	-1.7%	-0.8%	0.0%	-1.7%	-0.8%	0	0
15-Oct-2019	4.15	81.97	7942.851	4.3%	0.9%	1.3%	3.0%	-0.4%	0	0
16-Oct-2019	4.18	81.76	7920.209	0.7%	-0.3%	-0.3%	1.0%	0.0%	0	0
17-Oct-2019	4.75	81.67	7942.144	13.6%	-0.1%	0.3%	13.4%	-0.4%	1	0
18-Oct-2019	4.63	82.14	7868.491	-2.5%	0.6%	-0.9%	-1.6%	1.5%	0	0
21-Oct-2019	4.54	84.03	7940.331	-1.9%	2.3%	0.9%	-2.9%	1.4%	0	0
22-Oct-2019	4.44	84.26	7874.616	-2.2%	0.3%	-0.8%	-1.4%	1.1%	0	0
23-Oct-2019	4.77	84.18	7889.473	7.4%	-0.1%	0.2%	7.2%	-0.3%	0	0
24-Oct-2019	4.6	83.3	7966.719	-3.6%	-1.0%	1.0%	-4.5%	-2.0%	0	0
25-Oct-2019	4.65	84.07	8029.217	1.1%	0.9%	0.8%	0.3%	0.1%	0	0
28-Oct-2019	5.11	86.51	8110.669	9.9%	2.9%	1.0%	8.9%	1.9%	0	0
29-Oct-2019	4.63	86.99	8047.509	-9.4%	0.6%	-0.8%	-8.6%	1.3%	0	0
30-Oct-2019	4.72	90.99	8083.113	1.9%	4.6%	0.4%	1.5%	4.2%	0	0
31-Oct-2019	4.38	89.84	8083.832	-7.2%	-1.3%	0.0%	-7.2%	-1.3%	0	0
01-Nov-2019	4.69	89.96	8161.167	7.1%	0.1%	1.0%	6.1%	-0.8%	0	0
04-Nov-2019	4.92	90.14	8210.664	4.9%	0.2%	0.6%	4.3%	-0.4%	0	0
05-Nov-2019	4.66	91.57	8210.175	-5.3%	1.6%	0.0%	-5.3%	1.6%	0	0
06-Nov-2019	3.98	90.28	8196.028	-14.6%	-1.4%	-0.2%	-14.4%	-1.2%	1	0
07-Nov-2019	3.76	90.63	8219.646	-5.5%	0.4%	0.3%	-5.8%	0.1%	0	0
08-Nov-2019	3.59	91.61	8255.886	-4.5%	1.1%	0.4%	-5.0%	0.6%	0	0
11-Nov-2019	3.66	90.96	8241.912	1.9%	-0.7%	-0.2%	2.1%	-0.5%	0	0
12-Nov-2019	3.43	89.57	8263.789	-6.3%	-1.5%	0.3%	-6.5%	-1.8%	0	0
13-Nov-2019	3.72	88.49	8259.813	8.5%	-1.2%	0.0%	8.5%	-1.2%	0	0
14-Nov-2019	3.61	89.53	8257.831	-3.0%	1.2%	0.0%	-2.9%	1.2%	0	0
15-Nov-2019	3.61	90.43	8315.523	0.0%	1.0%	0.7%	-0.7%	0.3%	0	0
18-Nov-2019	3.45	90.66	8328.479	-4.4%	0.3%	0.2%	-4.6%	0.1%	0	0
19-Nov-2019	3.445	92.52	8338.737	-0.1%	2.1%	0.1%	-0.3%	1.9%	0	0
20-Nov-2019	3.55	94.83	8283.753	3.0%	2.5%	-0.7%	3.7%	3.2%	0	0
21-Nov-2019	3.64	93.4	8265.618	2.5%	-1.5%	-0.2%	2.8%	-1.3%	0	0
22-Nov-2019	3.72	93.01	8272.053	2.2%	-0.4%	0.1%	2.1%	-0.5%	0	0
25-Nov-2019	3.85	95.34	8371.928	3.5%	2.5%	1.2%	2.3%	1.3%	0	0
26-Nov-2019	3.93	93.54	8385.745	2.1%	-1.9%	0.2%	1.9%	-2.1%	0	0
27-Nov-2019	4.12	93.87	8444.709	4.8%	0.4%	0.7%	4.1%	-0.4%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
29-Nov-2019	4.35	92.26	8403.685	5.6%	-1.7%	-0.5%	6.1%	-1.2%	0	0
02-Dec-2019	4.2	91.82	8309.26	-3.4%	-0.5%	-1.1%	-2.3%	0.6%	0	0
03-Dec-2019	4.22	89.22	8254.737	0.5%	-2.8%	-0.7%	1.1%	-2.2%	0	0
04-Dec-2019	4.21	91.34	8296.529	-0.2%	2.4%	0.5%	-0.7%	1.9%	0	0
05-Dec-2019	4.11	90.23	8308.397	-2.4%	-1.2%	0.1%	-2.5%	-1.4%	0	0
06-Dec-2019	4.07	91.61	8397.367	-1.0%	1.5%	1.1%	-2.0%	0.5%	0	0
09-Dec-2019	3.89	91.05	8362.744	-4.4%	-0.6%	-0.4%	-4.0%	-0.2%	0	0
10-Dec-2019	3.93	93.03	8354.292	1.0%	2.2%	-0.1%	1.1%	2.3%	0	0
11-Dec-2019	3.89	92.49	8402.609	-1.0%	-0.6%	0.6%	-1.6%	-1.2%	0	0
12-Dec-2019	3.82	93.76	8466.894	-1.8%	1.4%	0.8%	-2.6%	0.6%	0	0
13-Dec-2019	3.65	89.63	8487.708	-4.5%	-4.4%	0.2%	-4.7%	-4.7%	0	1
16-Dec-2019	3.2	90.95	8570.334	-12.3%	1.5%	1.0%	-13.3%	0.5%	1	0
17-Dec-2019	3.33	89.43	8575.7	4.1%	-1.7%	0.1%	4.0%	-1.7%	0	0
18-Dec-2019	3.19	89.71	8580.624	-4.2%	0.3%	0.1%	-4.3%	0.3%	0	0
19-Dec-2019	3.07	89.46	8641.291	-3.8%	-0.3%	0.7%	-4.5%	-1.0%	0	0
20-Dec-2019	3.1	90.39	8678.491	1.0%	1.0%	0.4%	0.5%	0.6%	0	0
23-Dec-2019	3.13	90.9	8696.007	1.0%	0.6%	0.2%	0.8%	0.4%	0	0
24-Dec-2019	3.52	91.4	8699.506	12.5%	0.6%	0.0%	12.4%	0.5%	1	0
26-Dec-2019	5.05	89.46	8778.314	43.5%	-2.1%	0.9%	42.6%	-3.0%	1	0
27-Dec-2019	4.94	88.83	8770.979	-2.2%	-0.7%	-0.1%	-2.1%	-0.6%	0	0
30-Dec-2019	4.56	86.91	8709.727	-7.7%	-2.2%	-0.7%	-7.0%	-1.5%	0	0
31-Dec-2019	4.275	88.08	8733.073	-6.2%	1.3%	0.3%	-6.5%	1.1%	0	0
02-Jan-2020	4.4	87.66	8872.219	2.9%	-0.5%	1.6%	1.3%	-2.1%	0	0
03-Jan-2020	4.45	86.46	8793.904	1.1%	-1.4%	-0.9%	2.0%	-0.5%	0	0
06-Jan-2020	4.14	86.57	8848.515	-7.0%	0.1%	0.6%	-7.6%	-0.5%	0	0
07-Jan-2020	4.19	86.91	8846.449	1.2%	0.4%	0.0%	1.2%	0.4%	0	0
08-Jan-2020	4.08	87.16	8912.37	-2.6%	0.3%	0.7%	-3.4%	-0.5%	0	0
09-Jan-2020	4.15	87.57	8989.63	1.7%	0.5%	0.9%	0.8%	-0.4%	0	0
10-Jan-2020	4.53	85.67	8966.636	9.2%	-2.2%	-0.3%	9.4%	-1.9%	0	0
13-Jan-2020	5.55	86.2	9070.646	22.5%	0.6%	1.2%	21.4%	-0.5%	1	0
14-Jan-2020	5.23	91.79	9033.42	-5.8%	6.5%	-0.4%	-5.4%	6.9%	0	1
15-Jan-2020	5.96	92.44	9035.667	14.0%	0.7%	0.0%	13.9%	0.7%	1	0
16-Jan-2020	6.1	94.13	9124.999	2.3%	1.8%	1.0%	1.4%	0.8%	0	0
17-Jan-2020	6.42	93.13	9173.733	5.2%	-1.1%	0.5%	4.7%	-1.6%	0	0
21-Jan-2020	6.72	91.88	9166.628	4.7%	-1.3%	-0.1%	4.8%	-1.3%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
22-Jan-2020	7	92.44	9188.575	4.2%	0.6%	0.2%	3.9%	0.4%	0	0
23-Jan-2020	7.15	90.87	9216.984	2.1%	-1.7%	0.3%	1.8%	-2.0%	0	0
24-Jan-2020	6.52	89.33	9141.467	-8.8%	-1.7%	-0.8%	-8.0%	-0.9%	0	0
27-Jan-2020	5.99	90.05	8952.178	-8.1%	0.8%	-2.1%	-6.1%	2.9%	0	0
28-Jan-2020	5.53	93.2	9090.932	-7.7%	3.5%	1.5%	-9.2%	1.9%	0	0
29-Jan-2020	5.95	96.42	9101.613	7.6%	3.5%	0.1%	7.5%	3.3%	0	0
30-Jan-2020	5.68	96.35	9136.087	-4.5%	-0.1%	0.4%	-4.9%	-0.5%	0	0
31-Jan-2020	5.81	97.67	8991.512	2.3%	1.4%	-1.6%	3.9%	3.0%	0	0
03-Feb-2020	6.26	95.56	9126.232	7.7%	-2.2%	1.5%	6.2%	-3.7%	0	0
04-Feb-2020	6.54	96.65	9334.055	4.5%	1.1%	2.3%	2.2%	-1.1%	0	0
05-Feb-2020	6.255	101.47	9367.481	-4.4%	5.0%	0.4%	-4.7%	4.6%	0	1
06-Feb-2020	6.18	101.44	9445.916	-1.2%	0.0%	0.8%	-2.0%	-0.9%	0	0
07-Feb-2020	6.04	100.52	9401.097	-2.3%	-0.9%	-0.5%	-1.8%	-0.4%	0	0
10-Feb-2020	5.39	100.02	9516.84	-10.8%	-0.5%	1.2%	-12.0%	-1.7%	1	0
11-Feb-2020	5.52	101.15	9517.861	2.4%	1.1%	0.0%	2.4%	1.1%	0	0
12-Feb-2020	5.35	104.46	9613.201	-3.1%	3.3%	1.0%	-4.1%	2.3%	0	0
13-Feb-2020	5.12	103.99	9595.702	-4.3%	-0.4%	-0.2%	-4.1%	-0.3%	0	0
14-Feb-2020	5.04	104.19	9623.58	-1.6%	0.2%	0.3%	-1.9%	-0.1%	0	0
18-Feb-2020	5.25	105.98	9629.802	4.2%	1.7%	0.1%	4.1%	1.7%	0	0
19-Feb-2020	5.22	106.92	9718.726	-0.6%	0.9%	0.9%	-1.5%	0.0%	0	0
20-Feb-2020	5.2	107.42	9627.83	-0.4%	0.5%	-0.9%	0.6%	1.4%	0	0
21-Feb-2020	5.1	106.96	9446.688	-1.9%	-0.4%	-1.9%	0.0%	1.5%	0	0
24-Feb-2020	5	115.35	9079.632	-2.0%	7.8%	-3.9%	1.9%	11.7%	0	1
25-Feb-2020	4.87	112.86	8834.865	-2.6%	-2.2%	-2.7%	0.1%	0.5%	0	0
26-Feb-2020	4.8	105.81	8873.757	-1.4%	-6.2%	0.4%	-1.9%	-6.7%	0	1
27-Feb-2020	4.16	100.79	8436.666	-13.3%	-4.7%	-4.9%	-8.4%	0.2%	0	0
28-Feb-2020	4.13	102.96	8461.834	-0.7%	2.2%	0.3%	-1.0%	1.9%	0	0
02-Mar-2020	4.16	103.83	8877.978	0.7%	0.8%	4.9%	-4.2%	-4.1%	0	0
03-Mar-2020	4.04	100.21	8594.492	-2.9%	-3.5%	-3.2%	0.3%	-0.3%	0	0
04-Mar-2020	4.65	103.25	8949.281	15.1%	3.0%	4.1%	11.0%	-1.1%	0	0
05-Mar-2020	4.17	101.22	8671.658	-10.3%	-2.0%	-3.1%	-7.2%	1.1%	0	0
06-Mar-2020	4.04	98.26	8530.337	-3.1%	-2.9%	-1.6%	-1.5%	-1.3%	0	0
09-Mar-2020	3.7	91.29	7948.027	-8.4%	-7.1%	-6.8%	-1.6%	-0.3%	0	0
10-Mar-2020	3.56	100.49	8372.265	-3.8%	10.1%	5.3%	-9.1%	4.7%	0	1
11-Mar-2020	3.66	93.99	8006.119	2.8%	-6.5%	-4.4%	7.2%	-2.1%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
12-Mar-2020	3.505	86.14	7263.653	-4.2%	-8.4%	-9.3%	5.0%	0.9%	0	0
13-Mar-2020	4	91.91	7995.263	14.1%	6.7%	10.1%	4.1%	-3.4%	0	0
16-Mar-2020	3.62	79.43	7020.377	-9.5%	-13.6%	-12.2%	2.7%	-1.4%	0	0
17-Mar-2020	3.8	80.56	7473.95	5.0%	1.4%	6.5%	-1.5%	-5.0%	0	1
18-Mar-2020	3.31	79.39	7175.176	-12.9%	-1.5%	-4.0%	-8.9%	2.5%	0	0
19-Mar-2020	3.98	83.62	7288.523	20.2%	5.3%	1.6%	18.7%	3.7%	1	0
20-Mar-2020	4.11	83.14	6994.291	3.3%	-0.6%	-4.0%	7.3%	3.5%	0	0
23-Mar-2020	4.42	83.95	7006.917	7.5%	1.0%	0.2%	7.4%	0.8%	0	0
24-Mar-2020	4.28	88.04	7553.825	-3.2%	4.9%	7.8%	-11.0%	-2.9%	0	0
25-Mar-2020	4.19	90.54	7469.615	-2.1%	2.8%	-1.1%	-1.0%	4.0%	0	0
26-Mar-2020	4.87	92.02	7897.128	16.2%	1.6%	5.7%	10.5%	-4.1%	0	0
27-Mar-2020	4.65	91.32	7588.373	-4.5%	-0.8%	-3.9%	-0.6%	3.1%	0	0
30-Mar-2020	4.93	97.07	7889.006	6.0%	6.3%	4.0%	2.1%	2.3%	0	0
31-Mar-2020	4.71	94.825	7813.499	-4.5%	-2.3%	-1.0%	-3.5%	-1.4%	0	0
01-Apr-2020	4.86	93.9	7486.287	3.2%	-1.0%	-4.2%	7.4%	3.2%	0	0
02-Apr-2020	5.19	93.53	7635.658	6.8%	-0.4%	2.0%	4.8%	-2.4%	0	0
03-Apr-2020	4.95	92.74	7528.114	-4.6%	-0.8%	-1.4%	-3.2%	0.6%	0	0
06-Apr-2020	5.6	95.76	8081.663	13.1%	3.3%	7.4%	5.8%	-4.1%	0	0
07-Apr-2020	4.92	95.06	8049.307	-12.1%	-0.7%	-0.4%	-11.7%	-0.3%	1	0
08-Apr-2020	5.76	96.59	8229.542	17.1%	1.6%	2.2%	14.8%	-0.6%	1	0
09-Apr-2020	5.5	95.87	8238.529	-4.5%	-0.7%	0.1%	-4.6%	-0.9%	0	0
13-Apr-2020	6.08	98.25	8332.738	10.5%	2.5%	1.1%	9.4%	1.3%	0	0
14-Apr-2020	6.23	99.01	8692.155	2.5%	0.8%	4.3%	-1.8%	-3.5%	0	0
15-Apr-2020	6.49	97.41	8591.958	4.2%	-1.6%	-1.2%	5.3%	-0.5%	0	0
16-Apr-2020	6.99	97.27	8757.832	7.7%	-0.1%	1.9%	5.8%	-2.1%	0	0
17-Apr-2020	7.3	104.62	8832.414	4.4%	7.6%	0.9%	3.6%	6.7%	0	1
20-Apr-2020	6.18	106.44	8726.513	-15.3%	1.7%	-1.2%	-14.1%	2.9%	1	0
21-Apr-2020	6.17	104	8403.003	-0.2%	-2.3%	-3.7%	3.5%	1.4%	0	0
22-Apr-2020	6.18	108.07	8664.635	0.2%	3.9%	3.1%	-3.0%	0.8%	0	0
23-Apr-2020	5.93	109.99	8641.497	-4.0%	1.8%	-0.3%	-3.8%	2.0%	0	0
24-Apr-2020	6	111.21	8786.603	1.2%	1.1%	1.7%	-0.5%	-0.6%	0	0
27-Apr-2020	5.8	111.58	8837.657	-3.3%	0.3%	0.6%	-3.9%	-0.2%	0	0
28-Apr-2020	5.6	109.74	8677.6	-3.4%	-1.6%	-1.8%	-1.6%	0.2%	0	0
29-Apr-2020	5.64	107.97	8982.761	0.7%	-1.6%	3.5%	-2.8%	-5.1%	0	1
30-Apr-2020	4.98	109.56	9000.509	-11.7%	1.5%	0.2%	-11.9%	1.3%	1	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
01-May-2020	5.13	109.12	8718.179	3.0%	-0.4%	-3.1%	6.1%	2.7%	0	0
04-May-2020	5.18	111.91	8834.111	1.0%	2.6%	1.3%	-0.4%	1.2%	0	0
05-May-2020	6.47	111.56	8930.618	24.9%	-0.3%	1.1%	23.8%	-1.4%	1	0
06-May-2020	5.81	112.96	8984.859	-10.2%	1.3%	0.6%	-10.8%	0.6%	0	0
07-May-2020	6.38	111.98	9101.876	9.8%	-0.9%	1.3%	8.5%	-2.2%	0	0
08-May-2020	6.78	113.43	9220.354	6.3%	1.3%	1.3%	5.0%	0.0%	0	0
11-May-2020	7.43	115.66	9298.923	9.6%	2.0%	0.9%	8.7%	1.1%	0	0
12-May-2020	7.32	114.25	9112.447	-1.5%	-1.2%	-2.0%	0.5%	0.8%	0	0
13-May-2020	7.79	113.08	9000.077	6.4%	-1.0%	-1.2%	7.7%	0.2%	0	0
14-May-2020	7.49	113.43	9094.425	-3.9%	0.3%	1.0%	-4.9%	-0.7%	0	0
15-May-2020	7.37	116.36	9152.639	-1.6%	2.6%	0.6%	-2.2%	1.9%	0	0
18-May-2020	7.95	119.26	9331.926	7.9%	2.5%	2.0%	5.9%	0.5%	0	0
19-May-2020	7.87	118.44	9298.544	-1.0%	-0.7%	-0.4%	-0.6%	-0.3%	0	0
20-May-2020	9.3	120.18	9485.02	18.2%	1.5%	2.0%	16.2%	-0.5%	1	0
21-May-2020	8	117.2	9377.992	-14.0%	-2.5%	-1.1%	-12.9%	-1.4%	1	0
22-May-2020	8.44	117.57	9413.988	5.5%	0.3%	0.4%	5.1%	-0.1%	0	0
26-May-2020	8.87	118.45	9389.977	5.1%	0.7%	-0.3%	5.3%	1.0%	0	0
27-May-2020	9.06	116.81	9442.046	2.1%	-1.4%	0.6%	1.6%	-1.9%	0	0
28-May-2020	9.48	115	9416.713	4.6%	-1.5%	-0.3%	4.9%	-1.3%	0	0
29-May-2020	9.24	117.95	9555.525	-2.5%	2.6%	1.5%	-4.0%	1.1%	0	0
01-Jun-2020	9.59	120.28	9598.887	3.8%	2.0%	0.5%	3.3%	1.5%	0	0
02-Jun-2020	10.13	123.06	9657.307	5.6%	2.3%	0.6%	5.0%	1.7%	0	0
03-Jun-2020	9.65	125.7	9704.688	-4.7%	2.1%	0.5%	-5.2%	1.7%	0	0
04-Jun-2020	9.46	122.42	9629.664	-2.0%	-2.6%	-0.8%	-1.2%	-1.8%	0	0
05-Jun-2020	7.56	123.64	9824.39	-20.1%	1.0%	2.0%	-22.1%	-1.0%	1	0
08-Jun-2020	8.61	125.82	9901.521	13.9%	1.8%	0.8%	13.1%	1.0%	1	0
09-Jun-2020	8.19	124.53	9967.174	-4.9%	-1.0%	0.7%	-5.5%	-1.7%	0	0
10-Jun-2020	7.69	122.86	10094.26	-6.1%	-1.3%	1.3%	-7.4%	-2.6%	0	0
11-Jun-2020	7.3	116.3	9588.479	-5.1%	-5.3%	-5.0%	-0.1%	-0.3%	0	0
12-Jun-2020	7.58	115.42	9663.775	3.8%	-0.8%	0.8%	3.1%	-1.5%	0	0
15-Jun-2020	8.16	113.73	9776.891	7.7%	-1.5%	1.2%	6.5%	-2.6%	0	0
16-Jun-2020	8.6	114.05	9949.366	5.4%	0.3%	1.8%	3.6%	-1.5%	0	0
17-Jun-2020	8.31	117.74	9982.479	-3.4%	3.2%	0.3%	-3.7%	2.9%	0	0
18-Jun-2020	9.08	115.65	10012.05	9.3%	-1.8%	0.3%	9.0%	-2.1%	0	0
19-Jun-2020	10.01	118.36	10008.64	10.2%	2.3%	0.0%	10.3%	2.4%	0	0



## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
22-Jun-2020	10.97	118.87	10130.33	9.6%	0.4%	1.2%	8.4%	-0.8%	0	0
23-Jun-2020	11.02	120.8	10209.82	0.5%	1.6%	0.8%	-0.3%	0.8%	0	0
24-Jun-2020	11	121.28	10002.7	-0.2%	0.4%	-2.0%	1.8%	2.4%	0	0
25-Jun-2020	11.44	124.18	10101.83	4.0%	2.4%	1.0%	3.0%	1.4%	0	0
26-Jun-2020	10.9	119.76	9849.356	-4.7%	-3.6%	-2.5%	-2.2%	-1.1%	0	0
29-Jun-2020	10.67	119.96	9961.163	-2.1%	0.2%	1.1%	-3.2%	-1.0%	0	0
30-Jun-2020	8.42	121	10156.85	-21.1%	0.9%	2.0%	-23.1%	-1.1%	1	0
01-Jul-2020	8.28	121	10279.25	-1.7%	0.0%	1.2%	-2.9%	-1.2%	0	0
02-Jul-2020	7.79	120.33	10341.89	-5.9%	-0.6%	0.6%	-6.5%	-1.2%	0	0
06-Jul-2020	7.88	119.04	10604.06	1.2%	-1.1%	2.5%	-1.4%	-3.6%	0	0
07-Jul-2020	7.87	118.6	10524.01	-0.1%	-0.4%	-0.8%	0.6%	0.4%	0	0
08-Jul-2020	7.55	117.78	10666.7	-4.1%	-0.7%	1.4%	-5.4%	-2.0%	0	0
09-Jul-2020	7.44	116.92	10754.59	-1.5%	-0.7%	0.8%	-2.3%	-1.6%	0	0
10-Jul-2020	7.435	117.44	10836.33	-0.1%	0.4%	0.8%	-0.8%	-0.3%	0	0
13-Jul-2020	6.935	115.95	10602.21	-6.7%	-1.3%	-2.2%	-4.6%	0.9%	0	0
14-Jul-2020	6.7	118.37	10689.52	-3.4%	2.1%	0.8%	-4.2%	1.3%	0	0
15-Jul-2020	6.6	121.13	10701.68	-1.5%	2.3%	0.1%	-1.6%	2.2%	0	0
16-Jul-2020	6.6	115.96	10626.46	0.0%	-4.3%	-0.7%	0.7%	-3.6%	0	0
17-Jul-2020	6.97	117.2	10645.22	5.6%	1.1%	0.2%	5.4%	0.9%	0	0
20-Jul-2020	6.94	115.34	10952.08	-0.4%	-1.6%	2.9%	-3.3%	-4.5%	0	1
21-Jul-2020	6.76	113.27	10833.07	-2.6%	-1.8%	-1.1%	-1.5%	-0.7%	0	0
22-Jul-2020	6.8	113.53	10870.75	0.6%	0.2%	0.3%	0.2%	-0.1%	0	0
23-Jul-2020	6.06	114.47	10580.59	-10.9%	0.8%	-2.7%	-8.2%	3.5%	0	0
24-Jul-2020	5.54	112.26	10483.13	-8.6%	-1.9%	-0.9%	-7.7%	-1.0%	0	0
27-Jul-2020	5.38	114.68	10674.38	-2.9%	2.2%	1.8%	-4.7%	0.3%	0	0
28-Jul-2020	5.44	113.16	10532.5	1.1%	-1.3%	-1.3%	2.4%	0.0%	0	0
29-Jul-2020	5.34	112.73	10662.98	-1.8%	-0.4%	1.2%	-3.1%	-1.6%	0	0
30-Jul-2020	5.36	113.5	10715.51	0.4%	0.7%	0.5%	-0.1%	0.2%	0	0
31-Jul-2020	5.53	111.47	10905.88	3.2%	-1.8%	1.8%	1.4%	-3.6%	0	0
03-Aug-2020	5.82	116.41	11055.08	5.2%	4.4%	1.4%	3.9%	3.1%	0	0
04-Aug-2020	5.69	114.09	11096.54	-2.2%	-2.0%	0.4%	-2.6%	-2.4%	0	0
05-Aug-2020	5.99	113.07	11125.44	5.3%	-0.9%	0.3%	5.0%	-1.2%	0	0
06-Aug-2020	6.08	112.2	11267.09	1.5%	-0.8%	1.3%	0.2%	-2.0%	0	0
07-Aug-2020	6.22	112.79	11139.39	2.3%	0.5%	-1.1%	3.4%	1.7%	0	0
10-Aug-2020	5.91	110.93	11085.17	-5.0%	-1.6%	-0.5%	-4.5%	-1.2%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
11-Aug-2020	5.39	109.15	10876.08	-8.8%	-1.6%	-1.9%	-6.9%	0.3%	0	0
12-Aug-2020	5.6	110.52	11157.72	3.9%	1.3%	2.6%	1.3%	-1.3%	0	0
13-Aug-2020	5.83	109.38	11178.37	4.1%	-1.0%	0.2%	3.9%	-1.2%	0	0
14-Aug-2020	5.69	109.47	11164.45	-2.4%	0.1%	-0.1%	-2.3%	0.2%	0	0
17-Aug-2020	5.77	110.75	11288.57	1.4%	1.2%	1.1%	0.3%	0.1%	0	0
18-Aug-2020	5.78	110.93	11399.03	0.2%	0.2%	1.0%	-0.8%	-0.8%	0	0
19-Aug-2020	5.61	107.12	11318.64	-2.9%	-3.4%	-0.7%	-2.2%	-2.7%	0	0
20-Aug-2020	5.97	106.62	11477.05	6.4%	-0.5%	1.4%	5.0%	-1.9%	0	0
21-Aug-2020	5.66	107.25	11555.16	-5.2%	0.6%	0.7%	-5.9%	-0.1%	0	0
24-Aug-2020	4.98	105.92	11626.17	-12.0%	-1.2%	0.6%	-12.6%	-1.9%	1	0
25-Aug-2020	5.14	105.05	11721.81	3.2%	-0.8%	0.8%	2.4%	-1.6%	0	0
26-Aug-2020	5.29	105.04	11971.94	2.9%	0.0%	2.1%	0.8%	-2.1%	0	0
27-Aug-2020	4.96	105.67	11926.16	-6.2%	0.6%	-0.4%	-5.9%	1.0%	0	0
28-Aug-2020	5.06	106.04	11995.86	2.0%	0.4%	0.6%	1.4%	-0.2%	0	0
31-Aug-2020	5.12	106.96	12110.7	1.2%	0.9%	1.0%	0.2%	-0.1%	0	0
01-Sep-2020	4.78	105.51	12292.86	-6.6%	-1.4%	1.5%	-8.1%	-2.9%	0	0
02-Sep-2020	4.46	109.12	12420.54	-6.7%	3.4%	1.0%	-7.7%	2.4%	0	0
03-Sep-2020	4.39	104.56	11771.37	-1.6%	-4.2%	-5.2%	3.7%	1.0%	0	0
04-Sep-2020	4.34	105.37	11622.13	-1.1%	0.8%	-1.3%	0.1%	2.0%	0	0
08-Sep-2020	4.45	102.71	11068.26	2.5%	-2.5%	-4.8%	7.3%	2.2%	0	0
09-Sep-2020	4.77	103.9	11395.85	7.2%	1.2%	3.0%	4.2%	-1.8%	0	0
10-Sep-2020	5.04	102.44	11154.12	5.7%	-1.4%	-2.1%	7.8%	0.7%	0	0
11-Sep-2020	4.88	102.52	11087.4	-3.2%	0.1%	-0.6%	-2.6%	0.7%	0	0
14-Sep-2020	5.22	104.84	11277.76	7.0%	2.3%	1.7%	5.3%	0.5%	0	0
15-Sep-2020	5.42	105.75	11438.87	3.8%	0.9%	1.4%	2.4%	-0.6%	0	0
16-Sep-2020	5.94	106.08	11247.6	9.6%	0.3%	-1.7%	11.3%	2.0%	0	0
17-Sep-2020	5.91	106.67	11080.95	-0.5%	0.6%	-1.5%	1.0%	2.0%	0	0
18-Sep-2020	5.81	105.69	10936.98	-1.7%	-0.9%	-1.3%	-0.4%	0.4%	0	0
21-Sep-2020	5.51	101.01	10980.22	-5.2%	-4.4%	0.4%	-5.6%	-4.8%	0	1
22-Sep-2020	5.22	102.29	11186.37	-5.3%	1.3%	1.9%	-7.1%	-0.6%	0	0
23-Sep-2020	4.89	100.55	10833.33	-6.3%	-1.7%	-3.2%	-3.2%	1.5%	0	0
24-Sep-2020	4.84	99.9	10896.47	-1.0%	-0.6%	0.6%	-1.6%	-1.2%	0	0
25-Sep-2020	5.05	100.45	11151.13	4.3%	0.6%	2.3%	2.0%	-1.8%	0	0
28-Sep-2020	4.75	101.51	11364.45	-5.9%	1.1%	1.9%	-7.9%	-0.9%	0	0
29-Sep-2020	4.9	101.04	11322.95	3.2%	-0.5%	-0.4%	3.5%	-0.1%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
30-Sep-2020	4.92	101	11418.06	0.4%	0.0%	0.8%	-0.4%	-0.9%	0	0
01-Oct-2020	5.32	103.17	11583.2	8.1%	2.1%	1.4%	6.7%	0.7%	0	0
02-Oct-2020	4.96	101.87	11255.69	-6.8%	-1.3%	-2.8%	-3.9%	1.6%	0	0
05-Oct-2020	4.97	105.69	11509.06	0.2%	3.7%	2.3%	-2.0%	1.5%	0	0
06-Oct-2020	4.96	103.07	11291.27	-0.2%	-2.5%	-1.9%	1.7%	-0.6%	0	0
07-Oct-2020	5.15	103.87	11503.19	3.8%	0.8%	1.9%	2.0%	-1.1%	0	0
08-Oct-2020	5.28	104.89	11550.94	2.5%	1.0%	0.4%	2.1%	0.6%	0	0
09-Oct-2020	5.38	104.01	11725.85	1.9%	-0.8%	1.5%	0.4%	-2.4%	0	0
12-Oct-2020	5.79	104.25	12088.11	7.6%	0.2%	3.1%	4.5%	-2.9%	0	0
13-Oct-2020	4.08	108.32	12083.17	-29.5%	3.9%	0.0%	-29.5%	3.9%	1	0
14-Oct-2020	3.34	109.96	11985.36	-18.1%	1.5%	-0.8%	-17.3%	2.3%	1	0
15-Oct-2020	2.99	113.03	11898.57	-10.5%	2.8%	-0.7%	-9.8%	3.5%	0	0
16-Oct-2020	2.86	115	11852.17	-4.3%	1.7%	-0.4%	-4.0%	2.1%	0	0
19-Oct-2020	3.41	116.47	11634.35	19.2%	1.3%	-1.8%	21.1%	3.1%	1	0
20-Oct-2020	4.17	119.17	11677.84	22.3%	2.3%	0.4%	21.9%	1.9%	1	0
21-Oct-2020	4.17	118.85	11665.37	0.0%	-0.3%	-0.1%	0.1%	-0.2%	0	0
22-Oct-2020	4.51	122.1	11662.91	8.2%	2.7%	0.0%	8.2%	2.8%	0	0
23-Oct-2020	4.545	122.78	11692.57	0.8%	0.6%	0.3%	0.5%	0.3%	0	0
26-Oct-2020	4.48	123.57	11504.52	-1.4%	0.6%	-1.6%	0.2%	2.3%	0	0
27-Oct-2020	4.27	123.4	11598.95	-4.7%	-0.1%	0.8%	-5.5%	-1.0%	0	0
28-Oct-2020	4.7	132.03	11142.76	10.1%	7.0%	-3.9%	14.0%	10.9%	1	1
29-Oct-2020	4.5	130.25	11350.74	-4.3%	-1.3%	1.9%	-6.1%	-3.2%	0	0
30-Oct-2020	4.62	134.23	11052.95	2.7%	3.1%	-2.6%	5.3%	5.7%	0	1
02-Nov-2020	3.34	133.98	11084.76	-27.7%	-0.2%	0.3%	-28.0%	-0.5%	1	0
03-Nov-2020	3.16	136.5	11279.91	-5.4%	1.9%	1.8%	-7.1%	0.1%	0	0
04-Nov-2020	3.32	139.47	11777.02	5.1%	2.2%	4.4%	0.7%	-2.2%	0	0
05-Nov-2020	3.77	137.71	12078.07	13.6%	-1.3%	2.6%	11.0%	-3.8%	0	0
06-Nov-2020	4.5	135.88	12091.35	19.4%	-1.3%	0.1%	19.3%	-1.4%	1	0
09-Nov-2020	4.52	136.26	11830.39	0.4%	0.3%	-2.2%	2.6%	2.4%	0	0
10-Nov-2020	4.53	139.28	11624.29	0.2%	2.2%	-1.7%	2.0%	4.0%	0	0
11-Nov-2020	4.86	140.15	11892.93	7.3%	0.6%	2.3%	5.0%	-1.7%	0	0
12-Nov-2020	4.19	139.97	11827.14	-13.8%	-0.1%	-0.6%	-13.2%	0.4%	1	0
13-Nov-2020	3.93	141.48	11937.85	-6.2%	1.1%	0.9%	-7.1%	0.1%	0	0
16-Nov-2020	3.62	142.93	12013.39	-7.9%	1.0%	0.6%	-8.5%	0.4%	0	0
17-Nov-2020	3.39	141.11	11977.49	-6.4%	-1.3%	-0.3%	-6.1%	-1.0%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
18-Nov-2020	3.38	137.48	11894.71	-0.3%	-2.6%	-0.7%	0.4%	-1.9%	0	0
19-Nov-2020	3.4	136.67	11985.43	0.6%	-0.6%	0.8%	-0.2%	-1.4%	0	0
20-Nov-2020	3.14	136.02	11906.44	-7.6%	-0.5%	-0.7%	-7.0%	0.2%	0	0
23-Nov-2020	3.075	137.77	11905.94	-2.1%	1.3%	0.0%	-2.1%	1.3%	0	0
24-Nov-2020	3.1	135.43	12079.81	0.8%	-1.7%	1.5%	-0.6%	-3.2%	0	0
25-Nov-2020	2.94	135.07	12152.22	-5.2%	-0.3%	0.6%	-5.8%	-0.9%	0	0
27-Nov-2020	3.03	135.54	12258.21	3.1%	0.3%	0.9%	2.2%	-0.5%	0	0
30-Nov-2020	2.79	132.64	12268.32	-7.9%	-2.1%	0.1%	-8.0%	-2.2%	0	0
01-Dec-2020	2.95	132.49	12455.33	5.7%	-0.1%	1.5%	4.2%	-1.6%	0	0
02-Dec-2020	2.95	131.28	12456.41	0.0%	-0.9%	0.0%	0.0%	-0.9%	0	0
03-Dec-2020	2.92	129.94	12467.13	-1.0%	-1.0%	0.1%	-1.1%	-1.1%	0	0
04-Dec-2020	2.9	133.47	12528.48	-0.7%	2.7%	0.5%	-1.2%	2.2%	0	0
07-Dec-2020	2.915	129.98	12596.47	0.5%	-2.6%	0.5%	0.0%	-3.2%	0	0
08-Dec-2020	2.93	135.08	12635.72	0.5%	3.9%	0.3%	0.2%	3.6%	0	0
09-Dec-2020	2.84	134.65	12364.64	-3.1%	-0.3%	-2.1%	-0.9%	1.8%	0	0
10-Dec-2020	2.91	137.21	12401.74	2.5%	1.9%	0.3%	2.2%	1.6%	0	0
11-Dec-2020	2.98	138.7	12375.41	2.4%	1.1%	-0.2%	2.6%	1.3%	0	0
14-Dec-2020	3	143.14	12462.21	0.7%	3.2%	0.7%	0.0%	2.5%	0	0
15-Dec-2020	2.92	148.21	12595.92	-2.7%	3.5%	1.1%	-3.7%	2.5%	0	0
16-Dec-2020	3.05	146.25	12668.16	4.5%	-1.3%	0.6%	3.9%	-1.9%	0	0
17-Dec-2020	3.09	148.44	12752.06	1.3%	1.5%	0.7%	0.6%	0.8%	0	0
18-Dec-2020	3.13	146.85	12738.18	1.3%	-1.1%	-0.1%	1.4%	-1.0%	0	0
21-Dec-2020	3.13	146.13	12690.26	0.0%	-0.5%	-0.4%	0.4%	-0.1%	0	0
22-Dec-2020	2.97	146.35	12717.56	-5.1%	0.2%	0.2%	-5.3%	-0.1%	0	0
23-Dec-2020	2.92	149.36	12653.14	-1.7%	2.1%	-0.5%	-1.2%	2.6%	0	0
24-Dec-2020	2.82	149.83	12711.01	-3.4%	0.3%	0.5%	-3.9%	-0.1%	0	0
28-Dec-2020	2.6	150	12838.86	-7.8%	0.1%	1.0%	-8.8%	-0.9%	0	0
29-Dec-2020	2.77	149.54	12843.49	6.5%	-0.3%	0.0%	6.5%	-0.3%	0	0
30-Dec-2020	2.93	148.68	12845.36	5.8%	-0.6%	0.0%	5.8%	-0.6%	0	0
31-Dec-2020	2.95	151.79	12888.28	0.7%	2.1%	0.3%	0.3%	1.8%	0	0
04-Jan-2021	3	153.94	12694.67	1.7%	1.4%	-1.5%	3.2%	2.9%	0	0
05-Jan-2021	2.92	156.77	12802.38	-2.7%	1.8%	0.8%	-3.5%	1.0%	0	0
06-Jan-2021	3	163.51	12623.35	2.7%	4.3%	-1.4%	4.1%	5.7%	0	1
07-Jan-2021	3.07	167.05	12939.57	2.3%	2.2%	2.5%	-0.2%	-0.3%	0	0
08-Jan-2021	3	165.08	13105.2	-2.3%	-1.2%	1.3%	-3.6%	-2.5%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
11-Jan-2021	3	168.03	12902.49	0.0%	1.8%	-1.5%	1.5%	3.3%	0	0
12-Jan-2021	3.05	164.21	12892.09	1.7%	-2.3%	-0.1%	1.7%	-2.2%	0	0
13-Jan-2021	2.92	162.11	12973.63	-4.3%	-1.3%	0.6%	-4.9%	-1.9%	0	0
14-Jan-2021	3	167.26	12898.69	2.7%	3.2%	-0.6%	3.3%	3.8%	0	0
15-Jan-2021	2.94	172.82	12803.93	-2.0%	3.3%	-0.7%	-1.3%	4.1%	0	0
19-Jan-2021	2.97	171.61	12996.54	1.0%	-0.7%	1.5%	-0.5%	-2.2%	0	0
20-Jan-2021	2.95	171.17	13296.45	-0.7%	-0.3%	2.3%	-3.0%	-2.6%	0	0
21-Jan-2021	2.99	167.14	13404.99	1.4%	-2.4%	0.8%	0.5%	-3.2%	0	0
22-Jan-2021	2.93	167.71	13366.4	-2.0%	0.3%	-0.3%	-1.7%	0.6%	0	0
25-Jan-2021	2.97	169.35	13483.29	1.4%	1.0%	0.9%	0.5%	0.1%	0	0
26-Jan-2021	2.99	164.85	13490.19	0.7%	-2.7%	0.1%	0.6%	-2.7%	0	0
27-Jan-2021	2.81	155.79	13112.65	-6.0%	-5.5%	-2.8%	-3.2%	-2.7%	0	0
28-Jan-2021	2.85	164.39	13201.53	1.4%	5.5%	0.7%	0.7%	4.8%	0	1
29-Jan-2021	2.74	163.82	12925.38	-3.9%	-0.3%	-2.1%	-1.8%	1.7%	0	0
01-Feb-2021	2.74	168.22	13248.9	0.0%	2.7%	2.5%	-2.5%	0.2%	0	0
02-Feb-2021	2.88	169.81	13456.12	5.1%	0.9%	1.6%	3.5%	-0.6%	0	0
03-Feb-2021	2.94	169.92	13402.37	2.1%	0.1%	-0.4%	2.5%	0.5%	0	0
04-Feb-2021	3.31	167.83	13560.89	12.6%	-1.2%	1.2%	11.4%	-2.4%	1	0
05-Feb-2021	3.17	169.72	13603.96	-4.2%	1.1%	0.3%	-4.5%	0.8%	0	0
08-Feb-2021	3.47	169.3	13695.02	9.5%	-0.2%	0.7%	8.8%	-0.9%	0	0
09-Feb-2021	3.4	166.28	13687.09	-2.0%	-1.8%	-0.1%	-2.0%	-1.7%	0	0
10-Feb-2021	3.3	168.55	13655.27	-2.9%	1.4%	-0.2%	-2.7%	1.6%	0	0
11-Feb-2021	3.21	169.53	13734.35	-2.7%	0.6%	0.6%	-3.3%	0.0%	0	0
12-Feb-2021	3.27	167.64	13807.7	1.9%	-1.1%	0.5%	1.3%	-1.6%	0	0
16-Feb-2021	3.6	169.69	13773.77	10.1%	1.2%	-0.2%	10.3%	1.5%	0	0
17-Feb-2021	3.55	172.75	13699.71	-1.4%	1.8%	-0.5%	-0.9%	2.3%	0	0
18-Feb-2021	3.29	169.33	13637.51	-7.3%	-2.0%	-0.5%	-6.9%	-1.5%	0	0
19-Feb-2021	3.58	174.85	13580.78	8.8%	3.3%	-0.4%	9.2%	3.7%	0	0
22-Feb-2021	3.44	174.31	13223.74	-3.9%	-0.3%	-2.6%	-1.3%	2.3%	0	0
23-Feb-2021	3.13	172.38	13194.71	-9.0%	-1.1%	-0.2%	-8.8%	-0.9%	0	0
24-Feb-2021	3.31	173.7	13302.19	5.8%	0.8%	0.8%	4.9%	0.0%	0	0
25-Feb-2021	3.05	168.8	12828.31	-7.9%	-2.8%	-3.6%	-4.3%	0.7%	0	0
26-Feb-2021	2.8	167.18	12909.44	-8.2%	-1.0%	0.6%	-8.8%	-1.6%	0	0
01-Mar-2021	2.93	171.27	13282.95	4.6%	2.4%	2.9%	1.7%	-0.4%	0	0
02-Mar-2021	2.92	166.59	13059.95	-0.3%	-2.7%	-1.7%	1.3%	-1.1%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
03-Mar-2021	2.82	163.21	12683.33	-3.4%	-2.0%	-2.9%	-0.5%	0.9%	0	0
04-Mar-2021	2.66	160.34	12464	-5.7%	-1.8%	-1.7%	-3.9%	0.0%	0	0
05-Mar-2021	2.61	164.34	12668.51	-1.9%	2.5%	1.6%	-3.5%	0.9%	0	0
08-Mar-2021	2.52	160.09	12299.08	-3.4%	-2.6%	-2.9%	-0.5%	0.3%	0	0
09-Mar-2021	2.75	159.01	12794.49	9.1%	-0.7%	4.0%	5.1%	-4.7%	0	1
10-Mar-2021	2.84	159.68	12752.07	3.3%	0.4%	-0.3%	3.6%	0.8%	0	0
11-Mar-2021	2.91	158.82	13052.9	2.5%	-0.5%	2.4%	0.1%	-2.9%	0	0
12-Mar-2021	2.85	159.5	12937.29	-2.1%	0.4%	-0.9%	-1.2%	1.3%	0	0
15-Mar-2021	2.9	164.1	13082.54	1.8%	2.9%	1.1%	0.6%	1.8%	0	0
16-Mar-2021	2.88	166.57	13152.28	-0.7%	1.5%	0.5%	-1.2%	1.0%	0	0
17-Mar-2021	2.86	171.17	13202.38	-0.7%	2.8%	0.4%	-1.1%	2.4%	0	0
18-Mar-2021	2.77	170.35	12789.14	-3.1%	-0.5%	-3.1%	0.0%	2.7%	0	0
19-Mar-2021	2.77	170.11	12866.99	0.0%	-0.1%	0.6%	-0.6%	-0.7%	0	0
22-Mar-2021	2.71	168.36	13086.51	-2.2%	-1.0%	1.7%	-3.9%	-2.7%	0	0
23-Mar-2021	2.55	164.93	13017.79	-5.9%	-2.0%	-0.5%	-5.4%	-1.5%	0	0
24-Mar-2021	2.51	164.18	12798.88	-1.6%	-0.5%	-1.7%	0.1%	1.2%	0	0
25-Mar-2021	2.62	168.35	12780.51	4.4%	2.5%	-0.1%	4.5%	2.7%	0	0
26-Mar-2021	2.53	171.21	12979.12	-3.4%	1.7%	1.6%	-5.0%	0.1%	0	0
29-Mar-2021	2.42	169.49	12965.74	-4.3%	-1.0%	-0.1%	-4.2%	-0.9%	0	0
30-Mar-2021	2.54	165.47	12896.53	5.0%	-2.4%	-0.5%	5.5%	-1.8%	0	0
31-Mar-2021	2.69	167.27	13091.44	5.9%	1.1%	1.5%	4.4%	-0.4%	0	0
01-Apr-2021	2.76	192.34	13329.52	2.6%	15.0%	1.8%	0.8%	13.2%	0	1
05-Apr-2021	2.81	192.75	13598.16	1.8%	0.2%	2.0%	-0.2%	-1.8%	0	0
06-Apr-2021	2.7	191.65	13578.46	-3.9%	-0.6%	-0.1%	-3.8%	-0.4%	0	0
07-Apr-2021	2.51	191.1	13616.7	-7.0%	-0.3%	0.3%	-7.3%	-0.6%	0	0
08-Apr-2021	2.53	200.73	13758.51	0.8%	5.0%	1.0%	-0.2%	4.0%	0	0
09-Apr-2021	2.58	203.36	13845.06	2.0%	1.3%	0.6%	1.3%	0.7%	0	0
12-Apr-2021	2.52	198.59	13819.35	-2.3%	-2.3%	-0.2%	-2.1%	-2.2%	0	0
13-Apr-2021	2.56	199.3	13986.49	1.6%	0.4%	1.2%	0.4%	-0.9%	0	0
14-Apr-2021	2.62	202.78	13803.91	2.3%	1.7%	-1.3%	3.6%	3.1%	0	0
15-Apr-2021	2.74	201.67	14026.2	4.6%	-0.5%	1.6%	3.0%	-2.2%	0	0
16-Apr-2021	2.78	203.73	14041.91	1.5%	1.0%	0.1%	1.3%	0.9%	0	0
19-Apr-2021	2.71	203.84	13907.67	-2.5%	0.1%	-1.0%	-1.6%	1.0%	0	0
20-Apr-2021	2.83	207.58	13809.3	4.4%	1.8%	-0.7%	5.1%	2.5%	0	0
21-Apr-2021	2.89	211.93	13935.15	2.1%	2.1%	0.9%	1.2%	1.2%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
22-Apr-2021	2.77	209.33	13762.36	-4.2%	-1.2%	-1.2%	-2.9%	0.0%	0	0
23-Apr-2021	2.84	207.5	13941.44	2.5%	-0.9%	1.3%	1.2%	-2.2%	0	0
26-Apr-2021	2.88	208.11	14026.16	1.4%	0.3%	0.6%	0.8%	-0.3%	0	0
27-Apr-2021	2.83	204.33	13960.28	-1.7%	-1.8%	-0.5%	-1.3%	-1.3%	0	0
28-Apr-2021	2.89	205.62	13901.62	2.1%	0.6%	-0.4%	2.5%	1.1%	0	0
29-Apr-2021	2.9	204.24	13970.21	0.3%	-0.7%	0.5%	-0.1%	-1.2%	0	0
30-Apr-2021	2.84	201.56	13860.76	-2.1%	-1.3%	-0.8%	-1.3%	-0.5%	0	0
03-May-2021	2.71	201.79	13799.72	-4.6%	0.1%	-0.4%	-4.1%	0.6%	0	0
04-May-2021	2.63	195.37	13544.67	-3.0%	-3.2%	-1.8%	-1.1%	-1.3%	0	0
05-May-2021	2.61	198.14	13503.37	-0.8%	1.4%	-0.3%	-0.5%	1.7%	0	0
06-May-2021	2.55	192.07	13613.73	-2.3%	-3.1%	0.8%	-3.1%	-3.9%	0	0
07-May-2021	2.65	195.42	13719.63	3.9%	1.7%	0.8%	3.1%	1.0%	0	0
10-May-2021	2.71	189.88	13359.08	2.3%	-2.8%	-2.6%	4.9%	-0.2%	0	0
11-May-2021	2.82	194.3	13351.27	4.1%	2.3%	-0.1%	4.1%	2.4%	0	0
12-May-2021	2.74	195.49	13001.63	-2.8%	0.6%	-2.6%	-0.2%	3.2%	0	0
13-May-2021	2.74	193.77	13109.15	0.0%	-0.9%	0.8%	-0.8%	-1.7%	0	0
14-May-2021	2.72	197.87	13393.12	-0.7%	2.1%	2.2%	-2.9%	-0.1%	0	0
17-May-2021	2.74	198.29	13312.91	0.7%	0.2%	-0.6%	1.3%	0.8%	0	0
18-May-2021	2.74	195.62	13217.68	0.0%	-1.3%	-0.7%	0.7%	-0.6%	0	0
19-May-2021	2.66	189.82	13237.91	-2.9%	-3.0%	0.2%	-3.1%	-3.1%	0	0
20-May-2021	2.8	191.09	13494.09	5.3%	0.7%	1.9%	3.3%	-1.3%	0	0
21-May-2021	2.95	188.72	13411.74	5.4%	-1.2%	-0.6%	6.0%	-0.6%	0	0
24-May-2021	3.11	188.61	13641.75	5.4%	-0.1%	1.7%	3.7%	-1.8%	0	0
25-May-2021	2.92	185.27	13657.73	-6.1%	-1.8%	0.1%	-6.2%	-1.9%	0	0
26-May-2021	2.97	184.57	13702.74	1.7%	-0.4%	0.3%	1.4%	-0.7%	0	0
27-May-2021	3.11	185.74	13657.85	4.7%	0.6%	-0.3%	5.0%	1.0%	0	0
28-May-2021	3.01	185.9	13686.51	-3.2%	0.1%	0.2%	-3.4%	-0.1%	0	0
01-Jun-2021	2.94	177.82	13654.59	-2.3%	-4.3%	-0.2%	-2.1%	-4.1%	0	0
02-Jun-2021	3.01	171.66	13675.79	2.4%	-3.5%	0.2%	2.2%	-3.6%	0	0
03-Jun-2021	2.99	175.24	13529.68	-0.7%	2.1%	-1.1%	0.4%	3.2%	0	0
04-Jun-2021	2.87	175.95	13770.78	-4.0%	0.4%	1.8%	-5.8%	-1.4%	0	0
07-Jun-2021	2.74	175.89	13802.89	-4.5%	0.0%	0.2%	-4.8%	-0.3%	0	0
08-Jun-2021	2.76	170.47	13810.86	0.7%	-3.1%	0.1%	0.7%	-3.1%	0	0
09-Jun-2021	2.74	174.75	13814.94	-0.7%	2.5%	0.0%	-0.8%	2.5%	0	0
10-Jun-2021	2.75	180.49	13960.35	0.4%	3.3%	1.1%	-0.7%	2.2%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
11-Jun-2021	2.72	179.12	13998.3	-1.1%	-0.8%	0.3%	-1.4%	-1.0%	0	0
14-Jun-2021	2.68	179.65	14128.2	-1.5%	0.3%	0.9%	-2.4%	-0.6%	0	0
15-Jun-2021	2.66	178.45	14030.41	-0.7%	-0.7%	-0.7%	-0.1%	0.0%	0	0
16-Jun-2021	2.65	183.44	13983.01	-0.4%	2.8%	-0.3%	0.0%	3.1%	0	0
17-Jun-2021	2.68	182.41	14163.81	1.1%	-0.6%	1.3%	-0.2%	-1.9%	0	0
18-Jun-2021	2.61	178.49	14049.59	-2.6%	-2.1%	-0.8%	-1.8%	-1.3%	0	0
21-Jun-2021	2.53	180.2	14137.23	-3.1%	1.0%	0.6%	-3.7%	0.3%	0	0
22-Jun-2021	2.64	180.86	14270.42	4.3%	0.4%	0.9%	3.4%	-0.6%	0	0
23-Jun-2021	2.68	174.64	14274.24	1.5%	-3.4%	0.0%	1.5%	-3.5%	0	0
24-Jun-2021	2.85	175.75	14365.96	6.3%	0.6%	0.6%	5.7%	0.0%	0	0
25-Jun-2021	2.91	180	14345.18	2.1%	2.4%	-0.1%	2.2%	2.6%	0	0
28-Jun-2021	2.92	177.18	14524.98	0.3%	-1.6%	1.3%	-0.9%	-2.8%	0	0
29-Jun-2021	2.91	177	14572.75	-0.3%	-0.1%	0.3%	-0.7%	-0.4%	0	0
30-Jun-2021	2.86	179.41	14554.8	-1.7%	1.4%	-0.1%	-1.6%	1.5%	0	0
01-Jul-2021	2.82	184.67	14560.05	-1.4%	2.9%	0.0%	-1.4%	2.9%	0	0
02-Jul-2021	2.76	184.33	14727.63	-2.1%	-0.2%	1.2%	-3.3%	-1.3%	0	0
06-Jul-2021	2.59	185.27	14786.36	-6.2%	0.5%	0.4%	-6.6%	0.1%	0	0
07-Jul-2021	2.63	186.98	14810.54	1.5%	0.9%	0.2%	1.4%	0.8%	0	0
08-Jul-2021	2.59	183.98	14722.14	-1.5%	-1.6%	-0.6%	-0.9%	-1.0%	0	0
09-Jul-2021	2.67	187.65	14826.09	3.1%	2.0%	0.7%	2.4%	1.3%	0	0
12-Jul-2021	2.66	185.78	14877.89	-0.4%	-1.0%	0.3%	-0.7%	-1.3%	0	0
13-Jul-2021	2.64	183.55	14874.54	-0.8%	-1.2%	0.0%	-0.7%	-1.2%	0	0
14-Jul-2021	2.54	183.59	14900.44	-3.8%	0.0%	0.2%	-4.0%	-0.2%	0	0
15-Jul-2021	2.58	184.19	14794.69	1.6%	0.3%	-0.7%	2.3%	1.0%	0	0
16-Jul-2021	2.49	184.99	14681.38	-3.5%	0.4%	-0.8%	-2.7%	1.2%	0	0
19-Jul-2021	2.47	183.32	14549.09	-0.8%	-0.9%	-0.9%	0.1%	0.0%	0	0
20-Jul-2021	2.47	184.45	14728.21	0.0%	0.6%	1.2%	-1.2%	-0.6%	0	0
21-Jul-2021	2.54	182.78	14842.63	2.8%	-0.9%	0.8%	2.1%	-1.7%	0	0
22-Jul-2021	2.55	185.79	14940.17	0.4%	1.6%	0.7%	-0.3%	1.0%	0	0
23-Jul-2021	2.46	184.57	15111.79	-3.5%	-0.7%	1.1%	-4.7%	-1.8%	0	0
26-Jul-2021	2.44	183.27	15125.95	-0.8%	-0.7%	0.1%	-0.9%	-0.8%	0	0
27-Jul-2021	2.38	186.34	14956.97	-2.5%	1.7%	-1.1%	-1.3%	2.8%	0	0
28-Jul-2021	2.45	185.46	15018.1	2.9%	-0.5%	0.4%	2.5%	-0.9%	0	0
29-Jul-2021	2.39	184.22	15048.36	-2.4%	-0.7%	0.2%	-2.7%	-0.9%	0	0
30-Jul-2021	2.3	181.93	14959.9	-3.8%	-1.2%	-0.6%	-3.2%	-0.7%	0	0



## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
02-Aug-2021	2.36	179.86	14963.62	2.6%	-1.1%	0.0%	2.6%	-1.2%	0	0
03-Aug-2021	2.3	180.66	15061.42	-2.5%	0.4%	0.7%	-3.2%	-0.2%	0	0
04-Aug-2021	2.28	206.09	15083.39	-0.9%	14.1%	0.1%	-1.0%	13.9%	0	1
05-Aug-2021	2.38	205.42	15181.64	4.4%	-0.3%	0.7%	3.7%	-1.0%	0	0
06-Aug-2021	2.32	213.33	15109.36	-2.5%	3.9%	-0.5%	-2.0%	4.3%	0	0
09-Aug-2021	2.38	207.72	15133.11	2.6%	-2.6%	0.2%	2.4%	-2.8%	0	0
10-Aug-2021	2.41	204.34	15053.58	1.3%	-1.6%	-0.5%	1.8%	-1.1%	0	0
11-Aug-2021	2.36	202.21	15027.76	-2.1%	-1.0%	-0.2%	-1.9%	-0.9%	0	0
12-Aug-2021	2.58	203.05	15088.98	9.3%	0.4%	0.4%	8.9%	0.0%	0	0
13-Aug-2021	2.66	202.62	15136.68	3.1%	-0.2%	0.3%	2.8%	-0.5%	0	0
16-Aug-2021	2.61	199.47	15140.77	-1.9%	-1.6%	0.0%	-1.9%	-1.6%	0	0
17-Aug-2021	2.52	203.74	15002.83	-3.4%	2.1%	-0.9%	-2.5%	3.1%	0	0
18-Aug-2021	2.46	203.37	14857.92	-2.4%	-0.2%	-1.0%	-1.4%	0.8%	0	0
19-Aug-2021	2.43	201.05	14933.94	-1.2%	-1.1%	0.5%	-1.7%	-1.7%	0	0
20-Aug-2021	2.59	204.22	15092.57	6.6%	1.6%	1.1%	5.5%	0.5%	0	0
23-Aug-2021	2.62	206.92	15312.82	1.2%	1.3%	1.5%	-0.3%	-0.1%	0	0
24-Aug-2021	2.64	205.55	15357.68	0.8%	-0.7%	0.3%	0.5%	-1.0%	0	0
25-Aug-2021	2.67	205.46	15368.92	1.1%	0.0%	0.1%	1.1%	-0.1%	0	0
26-Aug-2021	2.73	205.75	15278.52	2.2%	0.1%	-0.6%	2.8%	0.7%	0	0
27-Aug-2021	2.7	211.08	15432.95	-1.1%	2.6%	1.0%	-2.1%	1.6%	0	0
30-Aug-2021	2.69	211.41	15605.09	-0.4%	0.2%	1.1%	-1.5%	-1.0%	0	0
31-Aug-2021	2.67	214.88	15582.51	-0.7%	1.6%	-0.1%	-0.6%	1.8%	0	0
01-Sep-2021	2.8	212.76	15611.57	4.9%	-1.0%	0.2%	4.7%	-1.2%	0	0
02-Sep-2021	2.81	212.31	15604.25	0.4%	-0.2%	0.0%	0.4%	-0.2%	0	0
03-Sep-2021	2.74	210.8	15652.86	-2.5%	-0.7%	0.3%	-2.8%	-1.0%	0	0
07-Sep-2021	2.72	207.98	15675.76	-0.7%	-1.3%	0.1%	-0.9%	-1.5%	0	0
08-Sep-2021	2.73	210.52	15620.85	0.4%	1.2%	-0.4%	0.7%	1.6%	0	0
09-Sep-2021	2.77	210.89	15561.05	1.5%	0.2%	-0.4%	1.8%	0.6%	0	0
10-Sep-2021	2.72	210.26	15440.75	-1.8%	-0.3%	-0.8%	-1.0%	0.5%	0	0
13-Sep-2021	2.71	209.62	15434.5	-0.4%	-0.3%	0.0%	-0.3%	-0.3%	0	0
14-Sep-2021	2.61	208.47	15382.9	-3.7%	-0.5%	-0.3%	-3.4%	-0.2%	0	0
15-Sep-2021	2.65	204.27	15503.53	1.5%	-2.0%	0.8%	0.7%	-2.8%	0	0
16-Sep-2021	2.65	205.14	15515.91	0.0%	0.4%	0.1%	-0.1%	0.3%	0	0
17-Sep-2021	2.69	200.08	15333.47	1.5%	-2.5%	-1.2%	2.7%	-1.3%	0	0
20-Sep-2021	2.56	198.51	15012.19	-4.8%	-0.8%	-2.1%	-2.7%	1.3%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
21-Sep-2021	2.6	198.83	15027.77	1.6%	0.2%	0.1%	1.5%	0.1%	0	0
22-Sep-2021	2.79	201.92	15176.51	7.3%	1.6%	1.0%	6.3%	0.6%	0	0
23-Sep-2021	2.78	200.47	15316.58	-0.4%	-0.7%	0.9%	-1.3%	-1.6%	0	0
24-Sep-2021	2.87	195.1	15329.68	3.2%	-2.7%	0.1%	3.2%	-2.8%	0	0
27-Sep-2021	2.95	195.28	15204.83	2.8%	0.1%	-0.8%	3.6%	0.9%	0	0
28-Sep-2021	2.91	187.66	14770.3	-1.4%	-3.9%	-2.9%	1.5%	-1.0%	0	0
29-Sep-2021	2.79	185.5	14752.89	-4.1%	-1.2%	-0.1%	-4.0%	-1.0%	0	0
30-Sep-2021	2.76	184.58	14689.62	-1.1%	-0.5%	-0.4%	-0.6%	-0.1%	0	0
01-Oct-2021	2.75	185.9	14791.87	-0.4%	0.7%	0.7%	-1.1%	0.0%	0	0
04-Oct-2021	2.81	185.37	14472.12	2.2%	-0.3%	-2.2%	4.3%	1.9%	0	0
05-Oct-2021	2.72	188.75	14674.15	-3.2%	1.8%	1.4%	-4.6%	0.4%	0	0
06-Oct-2021	2.71	191.77	14766.75	-0.4%	1.6%	0.6%	-1.0%	1.0%	0	0
07-Oct-2021	2.75	195.94	14897.13	1.5%	2.2%	0.9%	0.6%	1.3%	0	0
08-Oct-2021	2.73	195.38	14820.75	-0.7%	-0.3%	-0.5%	-0.2%	0.2%	0	0
11-Oct-2021	3.07	193.04	14713.73	12.5%	-1.2%	-0.7%	13.2%	-0.5%	1	0
12-Oct-2021	3.11	189.93	14662.11	1.3%	-1.6%	-0.4%	1.7%	-1.3%	0	0
13-Oct-2021	3.27	186.09	14774.6	5.1%	-2.0%	0.8%	4.4%	-2.8%	0	0
14-Oct-2021	3.26	187.6	15052.42	-0.3%	0.8%	1.9%	-2.2%	-1.1%	0	0
15-Oct-2021	3.2	187.07	15146.92	-1.8%	-0.3%	0.6%	-2.5%	-0.9%	0	0
18-Oct-2021	3.52	184.32	15300.89	10.0%	-1.5%	1.0%	9.0%	-2.5%	0	0
19-Oct-2021	3.49	186.36	15410.72	-0.9%	1.1%	0.7%	-1.6%	0.4%	0	0
20-Oct-2021	3.59	192.27	15388.71	2.9%	3.2%	-0.1%	3.0%	3.3%	0	0
21-Oct-2021	3.72	190.66	15489.59	3.6%	-0.8%	0.7%	3.0%	-1.5%	0	0
22-Oct-2021	3.59	191.01	15355.07	-3.5%	0.2%	-0.9%	-2.6%	1.1%	0	0
25-Oct-2021	3.59	191.34	15514.19	0.0%	0.2%	1.0%	-1.0%	-0.9%	0	0
26-Oct-2021	3.65	190.45	15559.49	1.7%	-0.5%	0.3%	1.4%	-0.8%	0	0
27-Oct-2021	3.58	186.14	15598.39	-1.9%	-2.3%	0.3%	-2.2%	-2.5%	0	0
28-Oct-2021	3.77	192.17	15778.16	5.3%	3.2%	1.2%	4.2%	2.1%	0	0
29-Oct-2021	3.75	190.76	15850.47	-0.5%	-0.7%	0.5%	-1.0%	-1.2%	0	0
01-Nov-2021	3.82	193.76	15905.28	1.9%	1.6%	0.3%	1.5%	1.2%	0	0
02-Nov-2021	3.92	192.2	15972.49	2.6%	-0.8%	0.4%	2.2%	-1.2%	0	0
03-Nov-2021	4.32	203.21	16144.5	10.2%	5.7%	1.1%	9.1%	4.7%	0	1
04-Nov-2021	4.31	201.44	16346.24	-0.2%	-0.9%	1.2%	-1.5%	-2.1%	0	0
05-Nov-2021	4.13	202.3	16359.38	-4.2%	0.4%	0.1%	-4.3%	0.3%	0	0
08-Nov-2021	4.3	202.09	16336.03	4.1%	-0.1%	-0.1%	4.3%	0.0%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
09-Nov-2021	4	198.93	16219.94	-7.0%	-1.6%	-0.7%	-6.3%	-0.9%	0	0
10-Nov-2021	4.23	202.5	15985.57	5.8%	1.8%	-1.4%	7.2%	3.2%	0	0
11-Nov-2021	5.17	200.9	16032.47	22.2%	-0.8%	0.3%	21.9%	-1.1%	1	0
12-Nov-2021	4.99	203.33	16199.89	-3.5%	1.2%	1.0%	-4.5%	0.2%	0	0
15-Nov-2021	4.86	205.03	16189.12	-2.6%	0.8%	-0.1%	-2.5%	0.9%	0	0
16-Nov-2021	4.81	203.24	16309.77	-1.0%	-0.9%	0.7%	-1.8%	-1.6%	0	0
17-Nov-2021	4.64	199.41	16308.07	-3.5%	-1.9%	0.0%	-3.5%	-1.9%	0	0
18-Nov-2021	4.62	202.61	16482.97	-0.4%	1.6%	1.1%	-1.5%	0.5%	0	0
19-Nov-2021	4.26	201.13	16573.34	-7.8%	-0.7%	0.5%	-8.3%	-1.3%	0	0
22-Nov-2021	4.08	198.91	16380.98	-4.2%	-1.1%	-1.2%	-3.1%	0.1%	0	0
23-Nov-2021	3.82	201.58	16306.72	-6.4%	1.3%	-0.5%	-5.9%	1.8%	0	0
24-Nov-2021	4.18	200.18	16367.81	9.4%	-0.7%	0.4%	9.0%	-1.1%	0	0
26-Nov-2021	4.11	193.64	16025.58	-1.7%	-3.3%	-2.1%	0.4%	-1.2%	0	0
29-Nov-2021	4.03	194	16399.24	-1.9%	0.2%	2.3%	-4.3%	-2.1%	0	0
30-Nov-2021	4.15	189.5	16135.92	3.0%	-2.3%	-1.6%	4.6%	-0.7%	0	0
01-Dec-2021	4.13	189.14	15877.72	-0.5%	-0.2%	-1.6%	1.1%	1.4%	0	0
02-Dec-2021	4	189.29	15990.76	-3.1%	0.1%	0.7%	-3.9%	-0.6%	0	0
03-Dec-2021	4.04	185.99	15712.04	1.0%	-1.7%	-1.7%	2.7%	0.0%	0	0
06-Dec-2021	4.01	188.72	15846.16	-0.7%	1.5%	0.9%	-1.6%	0.6%	0	0
07-Dec-2021	4.32	190.41	16325.66	7.7%	0.9%	3.0%	4.7%	-2.1%	0	0
08-Dec-2021	4.41	193.94	16394.34	2.1%	1.9%	0.4%	1.7%	1.4%	0	0
09-Dec-2021	4.35	187.04	16149.57	-1.4%	-3.6%	-1.5%	0.1%	-2.1%	0	0
10-Dec-2021	4.3	188.57	16331.98	-1.1%	0.8%	1.1%	-2.3%	-0.3%	0	0
13-Dec-2021	4.34	191.21	16082.55	0.9%	1.4%	-1.5%	2.5%	2.9%	0	0
14-Dec-2021	4.24	193.93	15914.9	-2.3%	1.4%	-1.0%	-1.3%	2.5%	0	0
15-Dec-2021	4.21	195.62	16289.6	-0.7%	0.9%	2.4%	-3.1%	-1.5%	0	0
16-Dec-2021	4.1	195.86	15863.94	-2.6%	0.1%	-2.6%	0.0%	2.7%	0	0
17-Dec-2021	4.14	196.06	15801.46	1.0%	0.1%	-0.4%	1.4%	0.5%	0	0
20-Dec-2021	4.14	202.22	15627.64	0.0%	3.1%	-1.1%	1.1%	4.2%	0	0
21-Dec-2021	4.19	205.12	15986.28	1.2%	1.4%	2.3%	-1.1%	-0.9%	0	0
22-Dec-2021	4.47	209.77	16180.14	6.7%	2.3%	1.2%	5.5%	1.1%	0	0
23-Dec-2021	4.67	214.04	16308.21	4.5%	2.0%	0.8%	3.7%	1.2%	0	0
27-Dec-2021	4.58	214.69	16567.5	-1.9%	0.3%	1.6%	-3.5%	-1.3%	0	0
28-Dec-2021	4.52	213.81	16488.66	-1.3%	-0.4%	-0.5%	-0.8%	0.1%	0	0
29-Dec-2021	4.77	215.02	16491.01	5.5%	0.6%	0.0%	5.5%	0.6%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
30-Dec-2021	4.98	215.18	16429.1	4.4%	0.1%	-0.4%	4.8%	0.4%	0	0
31-Dec-2021	4.87	216.08	16320.08	-2.2%	0.4%	-0.7%	-1.5%	1.1%	0	0
03-Jan-2022	5.14	210.63	16501.77	5.5%	-2.5%	1.1%	4.4%	-3.6%	0	0
04-Jan-2022	5.76	199.08	16279.73	12.1%	-5.5%	-1.3%	13.4%	-4.1%	1	0
05-Jan-2022	5.8	192.89	15771.78	0.7%	-3.1%	-3.1%	3.8%	0.0%	0	0
06-Jan-2022	6.35	196.07	15765.36	9.5%	1.6%	0.0%	9.5%	1.7%	0	0
07-Jan-2022	6.26	198.94	15592.19	-1.4%	1.5%	-1.1%	-0.3%	2.6%	0	0
10-Jan-2022	6.81	199.24	15614.43	8.8%	0.2%	0.1%	8.6%	0.0%	0	0
11-Jan-2022	6.6	206.25	15844.12	-3.1%	3.5%	1.5%	-4.6%	2.0%	0	0
12-Jan-2022	5.86	206.19	15905.1	-11.2%	0.0%	0.4%	-11.6%	-0.4%	1	0
13-Jan-2022	5.73	208	15495.62	-2.2%	0.9%	-2.6%	0.4%	3.5%	0	0
14-Jan-2022	6.25	213.96	15611.59	9.1%	2.9%	0.7%	8.3%	2.1%	0	0
18-Jan-2022	6.09	212.03	15210.76	-2.6%	-0.9%	-2.6%	0.0%	1.7%	0	0
19-Jan-2022	5.73	205.07	15047.84	-5.9%	-3.3%	-1.1%	-4.8%	-2.2%	0	0
20-Jan-2022	5.75	199.97	14846.46	0.3%	-2.5%	-1.3%	1.7%	-1.1%	0	0
21-Jan-2022	5.5	200.06	14438.4	-4.3%	0.0%	-2.7%	-1.6%	2.8%	0	0
24-Jan-2022	5.32	202.15	14509.58	-3.3%	1.0%	0.5%	-3.8%	0.6%	0	0
25-Jan-2022	5.68	199.72	14149.12	6.8%	-1.2%	-2.5%	9.3%	1.3%	0	0
26-Jan-2022	5.36	198.57	14172.76	-5.6%	-0.6%	0.2%	-5.8%	-0.7%	0	0
27-Jan-2022	5.32	195.17	14003.11	-0.7%	-1.7%	-1.2%	0.5%	-0.5%	0	0
28-Jan-2022	5.57	200.9	14454.61	4.7%	2.9%	3.2%	1.5%	-0.3%	0	0
31-Jan-2022	5.66	201.87	14930.05	1.6%	0.5%	3.3%	-1.7%	-2.8%	0	0
01-Feb-2022	6	202.97	15019.68	6.0%	0.5%	0.6%	5.4%	-0.1%	0	0
02-Feb-2022	5.82	202.12	15139.74	-3.0%	-0.4%	0.8%	-3.8%	-1.2%	0	0
03-Feb-2022	6.09	198.71	14501.11	4.6%	-1.7%	-4.2%	8.9%	2.5%	0	0
04-Feb-2022	6.25	201.59	14694.35	2.6%	1.4%	1.3%	1.3%	0.1%	0	0
07-Feb-2022	6.46	199.81	14571.25	3.4%	-0.9%	-0.8%	4.2%	0.0%	0	0
08-Feb-2022	6.61	199.64	14747.03	2.3%	-0.1%	1.2%	1.1%	-1.3%	0	0
09-Feb-2022	6.63	204.94	15056.96	0.3%	2.7%	2.1%	-1.8%	0.6%	0	0
10-Feb-2022	6.34	203.75	14705.64	-4.4%	-0.6%	-2.3%	-2.0%	1.8%	0	0
11-Feb-2022	6.09	203.57	14253.84	-3.9%	-0.1%	-3.1%	-0.9%	3.0%	0	0
14-Feb-2022	6	202.84	14268.6	-1.5%	-0.4%	0.1%	-1.6%	-0.5%	0	0
15-Feb-2022	6.4	204.29	14620.82	6.7%	0.7%	2.5%	4.2%	-1.8%	0	0
16-Feb-2022	6.34	204.56	14603.64	-0.9%	0.1%	-0.1%	-0.8%	0.2%	0	0
17-Feb-2022	5.85	199.91	14171.74	-7.7%	-2.3%	-3.0%	-4.8%	0.7%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
18-Feb-2022	5.57	196.5	14009.54	-4.8%	-1.7%	-1.1%	-3.6%	-0.6%	0	0
22-Feb-2022	5.47	193.68	13870.53	-1.8%	-1.4%	-1.0%	-0.8%	-0.4%	0	0
23-Feb-2022	5.21	193.11	13509.43	-4.8%	-0.3%	-2.6%	-2.1%	2.3%	0	0
24-Feb-2022	5.91	167.71	13974.67	13.4%	-13.2%	3.4%	10.0%	-16.6%	0	1
25-Feb-2022	5.93	168	14189.16	0.3%	0.2%	1.5%	-1.2%	-1.4%	0	0
28-Feb-2022	6.47	166.2	14237.81	9.1%	-1.1%	0.3%	8.8%	-1.4%	0	0
01-Mar-2022	6.5	166.16	14005.99	0.5%	0.0%	-1.6%	2.1%	1.6%	0	0
02-Mar-2022	6.87	175.35	14243.69	5.7%	5.5%	1.7%	4.0%	3.8%	0	0
03-Mar-2022	6.82	174.96	14035.21	-0.7%	-0.2%	-1.5%	0.7%	1.2%	0	0
04-Mar-2022	6.65	174.52	13837.83	-2.5%	-0.3%	-1.4%	-1.1%	1.2%	0	0
07-Mar-2022	6.485	172.85	13319.38	-2.5%	-1.0%	-3.7%	1.3%	2.8%	0	0
08-Mar-2022	6.9	172.48	13267.61	6.4%	-0.2%	-0.4%	6.8%	0.2%	0	0
09-Mar-2022	7.36	169.92	13742.2	6.7%	-1.5%	3.6%	3.1%	-5.1%	0	1
10-Mar-2022	7.38	167.78	13591	0.3%	-1.3%	-1.1%	1.4%	-0.2%	0	0
11-Mar-2022	6.22	173	13301.83	-15.7%	3.1%	-2.1%	-13.6%	5.2%	1	1
14-Mar-2022	5.95	175	13046.64	-4.3%	1.2%	-1.9%	-2.4%	3.1%	0	0
15-Mar-2022	6.17	178.82	13458.56	3.7%	2.2%	3.2%	0.5%	-1.0%	0	0
16-Mar-2022	6.42	182.55	13956.79	4.1%	2.1%	3.7%	0.3%	-1.6%	0	0
17-Mar-2022	6.74	184.49	14118.6	5.0%	1.1%	1.2%	3.8%	-0.1%	0	0
18-Mar-2022	7.14	181.2	14420.08	5.9%	-1.8%	2.1%	3.8%	-3.9%	0	0
21-Mar-2022	6.94	182.17	14376.09	-2.8%	0.5%	-0.3%	-2.5%	0.8%	0	0
22-Mar-2022	7.04	179.33	14654.33	1.4%	-1.6%	1.9%	-0.5%	-3.5%	0	0
23-Mar-2022	7.29	177.78	14447.55	3.6%	-0.9%	-1.4%	5.0%	0.5%	0	0
24-Mar-2022	7.35	178.87	14765.7	0.8%	0.6%	2.2%	-1.4%	-1.6%	0	0
25-Mar-2022	7.03	174.84	14754.31	-4.4%	-2.3%	-0.1%	-4.3%	-2.2%	0	0
28-Mar-2022	6.92	175.23	14987.4	-1.6%	0.2%	1.6%	-3.1%	-1.4%	0	0
29-Mar-2022	7.38	178.46	15239.32	6.6%	1.8%	1.7%	5.0%	0.2%	0	0
30-Mar-2022	7.33	175.63	15071.55	-0.7%	-1.6%	-1.1%	0.4%	-0.5%	0	0
31-Mar-2022	7.18	179.41	14838.49	-2.0%	2.2%	-1.5%	-0.5%	3.7%	0	0
01-Apr-2022	7.14	184.65	14861.21	-0.6%	2.9%	0.2%	-0.7%	2.8%	0	0
04-Apr-2022	7.055	184.03	15159.58	-1.2%	-0.3%	2.0%	-3.2%	-2.3%	0	0
05-Apr-2022	7.21	184.71	14820.64	2.2%	0.4%	-2.2%	4.4%	2.6%	0	0
06-Apr-2022	7.55	185.48	14498.89	4.7%	0.4%	-2.2%	6.9%	2.6%	0	0
07-Apr-2022	6.94	190.11	14531.81	-8.1%	2.5%	0.2%	-8.3%	2.3%	0	0
08-Apr-2022	6.63	189.27	14327.26	-4.5%	-0.4%	-1.4%	-3.1%	1.0%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
11-Apr-2022	6.3	185.54	13990.21	-5.0%	-2.0%	-2.4%	-2.6%	0.4%	0	0
12-Apr-2022	6.19	186.66	13940.24	-1.7%	0.6%	-0.4%	-1.4%	1.0%	0	0
13-Apr-2022	5.25	190.19	14217.29	-15.2%	1.9%	2.0%	-17.2%	-0.1%	1	0
14-Apr-2022	5.28	191.91	13893.22	0.6%	0.9%	-2.3%	2.9%	3.2%	0	0
18-Apr-2022	5.14	188.81	13910.76	-2.7%	-1.6%	0.1%	-2.8%	-1.7%	0	0
19-Apr-2022	5.45	184.24	14210.26	6.0%	-2.4%	2.2%	3.9%	-4.6%	0	1
20-Apr-2022	5.48	187.26	13998.53	0.6%	1.6%	-1.5%	2.0%	3.1%	0	0
21-Apr-2022	5.54	190.22	13720.45	1.1%	1.6%	-2.0%	3.1%	3.6%	0	0
22-Apr-2022	5.63	187.63	13356.87	1.6%	-1.4%	-2.6%	4.3%	1.3%	0	0
25-Apr-2022	5.82	186.24	13533.22	3.4%	-0.7%	1.3%	2.1%	-2.1%	0	0
26-Apr-2022	5.57	174.81	13009.71	-4.3%	-6.1%	-3.9%	-0.4%	-2.3%	0	0
27-Apr-2022	5.61	177.3	13003.36	0.7%	1.4%	0.0%	0.8%	1.5%	0	0
28-Apr-2022	5.69	179.34	13456.06	1.4%	1.2%	3.5%	-2.1%	-2.3%	0	0
29-Apr-2022	5.44	177.56	12854.8	-4.4%	-1.0%	-4.5%	0.1%	3.5%	0	0
02-May-2022	5.83	179.82	13075.85	7.2%	1.3%	1.7%	5.4%	-0.4%	0	0
03-May-2022	6	179.68	13089.9	2.9%	-0.1%	0.1%	2.8%	-0.2%	0	0
04-May-2022	5.97	186.36	13535.71	-0.5%	3.7%	3.4%	-3.9%	0.3%	0	0
05-May-2022	5.75	186.99	12850.55	-3.7%	0.3%	-5.1%	1.4%	5.4%	0	1
06-May-2022	5.65	184.09	12693.54	-1.7%	-1.6%	-1.2%	-0.5%	-0.3%	0	0
09-May-2022	5.04	178.58	12187.72	-10.8%	-3.0%	-4.0%	-6.8%	1.0%	0	0
10-May-2022	5.06	179.11	12345.86	0.4%	0.3%	1.3%	-0.9%	-1.0%	0	0
11-May-2022	4.93	179.49	11967.56	-2.6%	0.2%	-3.1%	0.5%	3.3%	0	0
12-May-2022	4.66	181.37	11945.5	-5.5%	1.0%	-0.2%	-5.3%	1.2%	0	0
13-May-2022	5.31	183.44	12387.4	13.9%	1.1%	3.7%	10.2%	-2.6%	0	0
16-May-2022	5.67	185.13	12243.58	6.8%	0.9%	-1.2%	7.9%	2.1%	0	0
17-May-2022	6.01	190.99	12564.1	6.0%	3.2%	2.6%	3.4%	0.5%	0	0
18-May-2022	5.61	185.38	11928.31	-6.7%	-2.9%	-5.1%	-1.6%	2.1%	0	0
19-May-2022	5.78	186.31	11875.63	3.0%	0.5%	-0.4%	3.5%	0.9%	0	0
20-May-2022	5.79	188.33	11835.62	0.2%	1.1%	-0.3%	0.5%	1.4%	0	0
23-May-2022	4.7	210.14	12034.28	-18.8%	11.6%	1.7%	-20.5%	9.9%	1	1
24-May-2022	3.37	218.95	11769.84	-28.3%	4.2%	-2.2%	-26.1%	6.4%	1	1
25-May-2022	3.65	228.39	11943.93	8.3%	4.3%	1.5%	6.8%	2.8%	0	0
26-May-2022	4.03	224.78	12276.79	10.4%	-1.6%	2.8%	7.6%	-4.4%	0	1
27-May-2022	4.07	235.83	12681.42	1.0%	4.9%	3.3%	-2.3%	1.6%	0	0
31-May-2022	4.06	230.34	12642.1	-0.2%	-2.3%	-0.3%	0.1%	-2.0%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
01-Jun-2022	3.89	231.29	12548.36	-4.2%	0.4%	-0.7%	-3.4%	1.2%	0	0
02-Jun-2022	4.36	228.23	12892.89	12.1%	-1.3%	2.7%	9.3%	-4.1%	0	0
03-Jun-2022	4.32	228.64	12548.03	-0.9%	0.2%	-2.7%	1.8%	2.9%	0	0
06-Jun-2022	4.02	225.84	12599.63	-6.9%	-1.2%	0.4%	-7.4%	-1.6%	0	0
07-Jun-2022	4.47	228.62	12711.68	11.2%	1.2%	0.9%	10.3%	0.3%	0	0
08-Jun-2022	4.42	228.73	12615.13	-1.1%	0.0%	-0.8%	-0.4%	0.8%	0	0
09-Jun-2022	4.14	221.16	12269.78	-6.3%	-3.3%	-2.7%	-3.6%	-0.6%	0	0
10-Jun-2022	4.09	220.65	11832.82	-1.2%	-0.2%	-3.6%	2.4%	3.3%	0	0
13-Jun-2022	3.95	216.46	11288.32	-3.4%	-1.9%	-4.6%	1.2%	2.7%	0	0
14-Jun-2022	4.3	218.24	11311.69	8.9%	0.8%	0.2%	8.7%	0.6%	0	0
15-Jun-2022	4.78	220.09	11593.77	11.2%	0.8%	2.5%	8.7%	-1.6%	0	0
16-Jun-2022	4.95	217.67	11127.57	3.6%	-1.1%	-4.0%	7.6%	2.9%	0	0
17-Jun-2022	4.86	219.38	11265.99	-1.8%	0.8%	1.2%	-3.1%	-0.5%	0	0
21-Jun-2022	4.7	228.84	11546.76	-3.3%	4.3%	2.5%	-5.8%	1.8%	0	0
22-Jun-2022	4.58	232.31	11527.71	-2.6%	1.5%	-0.2%	-2.4%	1.7%	0	0
23-Jun-2022	4.64	240.86	11697.68	1.3%	3.7%	1.5%	-0.2%	2.2%	0	0
24-Jun-2022	4.34	238.95	12105.85	-6.5%	-0.8%	3.5%	-10.0%	-4.3%	0	0
27-Jun-2022	4.48	241.14	12008.24	3.2%	0.9%	-0.8%	4.0%	1.7%	0	0
28-Jun-2022	4.38	234.02	11637.77	-2.2%	-3.0%	-3.1%	0.9%	0.1%	0	0
29-Jun-2022	4.35	238.29	11658.26	-0.7%	1.8%	0.2%	-0.9%	1.6%	0	0
30-Jun-2022	4.36	235.64	11503.72	0.2%	-1.1%	-1.3%	1.6%	0.2%	0	0
01-Jul-2022	4.24	238	11585.68	-2.8%	1.0%	0.7%	-3.5%	0.3%	0	0
05-Jul-2022	4.23	237.15	11779.91	-0.2%	-0.4%	1.7%	-1.9%	-2.0%	0	0
06-Jul-2022	4.2	241.9	11852.59	-0.7%	2.0%	0.6%	-1.3%	1.4%	0	0
07-Jul-2022	4.27	240.2	12109.05	1.7%	-0.7%	2.2%	-0.5%	-2.9%	0	0
08-Jul-2022	4.27	244.17	12125.69	0.0%	1.7%	0.1%	-0.1%	1.5%	0	0
11-Jul-2022	4.2	241.79	11860.28	-1.6%	-1.0%	-2.2%	0.5%	1.2%	0	0
12-Jul-2022	3.93	239.72	11744.99	-6.4%	-0.9%	-1.0%	-5.5%	0.1%	0	0
13-Jul-2022	3.91	236.83	11728.53	-0.5%	-1.2%	-0.1%	-0.4%	-1.1%	0	0
14-Jul-2022	3.78	237.13	11768.4	-3.3%	0.1%	0.3%	-3.7%	-0.2%	0	0
15-Jul-2022	3.89	240.08	11983.62	2.9%	1.2%	1.8%	1.1%	-0.6%	0	0
18-Jul-2022	3.73	234.11	11877.5	-4.1%	-2.5%	-0.9%	-3.2%	-1.6%	0	0
19-Jul-2022	5.42	231.43	12249.42	45.3%	-1.1%	3.1%	42.2%	-4.3%	1	0
20-Jul-2022	5.29	226.13	12439.68	-2.4%	-2.3%	1.6%	-4.0%	-3.8%	0	0
21-Jul-2022	5.03	226.2	12619.41	-4.9%	0.0%	1.4%	-6.4%	-1.4%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
22-Jul-2022	5.2	225.45	12396.47	3.4%	-0.3%	-1.8%	5.1%	1.4%	0	0
25-Jul-2022	5.11	227.98	12328.41	-1.7%	1.1%	-0.5%	-1.2%	1.7%	0	0
26-Jul-2022	5.06	231.44	12086.9	-1.0%	1.5%	-2.0%	1.0%	3.5%	0	0
27-Jul-2022	5.37	231	12601.47	6.1%	-0.2%	4.3%	1.9%	-4.4%	0	1
28-Jul-2022	5.12	229.99	12717.87	-4.7%	-0.4%	0.9%	-5.6%	-1.4%	0	0
29-Jul-2022	4.905	231.07	12947.98	-4.2%	0.5%	1.8%	-6.0%	-1.3%	0	0
01-Aug-2022	4.97	225.3	12940.78	1.3%	-2.5%	-0.1%	1.4%	-2.4%	0	0
02-Aug-2022	5.22	224.75	12901.6	5.0%	-0.2%	-0.3%	5.3%	0.1%	0	0
03-Aug-2022	5.21	228.52	13253.26	-0.2%	1.7%	2.7%	-2.9%	-1.0%	0	0
04-Aug-2022	5.23	221.35	13311.04	0.4%	-3.1%	0.4%	-0.1%	-3.6%	0	0
05-Aug-2022	5.37	221.65	13207.69	2.7%	0.1%	-0.8%	3.5%	0.9%	0	0
08-Aug-2022	5.35	218.73	13159.16	-0.4%	-1.3%	-0.4%	0.0%	-0.9%	0	0
09-Aug-2022	5.47	219.17	13008.17	2.2%	0.2%	-1.1%	3.4%	1.3%	0	0
10-Aug-2022	5.54	221.49	13378.32	1.3%	1.1%	2.8%	-1.6%	-1.8%	0	0
11-Aug-2022	5.71	220.41	13291.99	3.1%	-0.5%	-0.6%	3.7%	0.2%	0	0
12-Aug-2022	7.3	217.1	13565.87	27.8%	-1.5%	2.1%	25.8%	-3.6%	1	0
15-Aug-2022	8.39	218.36	13667.18	14.9%	0.6%	0.7%	14.2%	-0.2%	1	0
16-Aug-2022	7.45	221.66	13635.21	-11.2%	1.5%	-0.2%	-11.0%	1.7%	0	0
17-Aug-2022	7.2	221.63	13470.86	-3.4%	0.0%	-1.2%	-2.2%	1.2%	0	0
18-Aug-2022	7.7	223.44	13505.99	6.9%	0.8%	0.3%	6.7%	0.6%	0	0
19-Aug-2022	7.44	224.44	13242.9	-3.4%	0.4%	-1.9%	-1.4%	2.4%	0	0
22-Aug-2022	7.62	220.31	12890.54	2.4%	-1.8%	-2.7%	5.1%	0.8%	0	0
23-Aug-2022	7.3	226.51	12881.79	-4.2%	2.8%	-0.1%	-4.1%	2.9%	0	0
24-Aug-2022	7.44	222.49	12917.86	1.9%	-1.8%	0.3%	1.6%	-2.1%	0	0
25-Aug-2022	7.34	220.78	13143.58	-1.3%	-0.8%	1.7%	-3.1%	-2.5%	0	0
26-Aug-2022	7.51	215.3	12605.17	2.3%	-2.5%	-4.1%	6.4%	1.6%	0	0
29-Aug-2022	7.73	217.49	12484.32	2.9%	1.0%	-1.0%	3.9%	2.0%	0	0
30-Aug-2022	5.38	218.97	12342.7	-30.4%	0.7%	-1.1%	-29.3%	1.8%	1	0
31-Aug-2022	5.77	226.62	12272.03	7.2%	3.5%	-0.6%	7.8%	4.1%	0	0
01-Sep-2022	4.86	226.07	12274.63	-15.8%	-0.2%	0.0%	-15.8%	-0.3%	1	0
02-Sep-2022	5.86	222.91	12098.44	20.6%	-1.4%	-1.4%	22.0%	0.0%	1	0
06-Sep-2022	5.62	222.35	12011.31	-4.1%	-0.3%	-0.7%	-3.4%	0.5%	0	0
07-Sep-2022	5.79	222.08	12259.39	3.0%	-0.1%	2.1%	1.0%	-2.2%	0	0
08-Sep-2022	6.13	223.71	12321.19	5.9%	0.7%	0.5%	5.4%	0.2%	0	0
09-Sep-2022	6.09	223.48	12588.29	-0.7%	-0.1%	2.2%	-2.8%	-2.3%	0	0



## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
12-Sep-2022	5.95	221.94	12739.72	-2.3%	-0.7%	1.2%	-3.5%	-1.9%	0	0
13-Sep-2022	5.91	216.57	12033.62	-0.7%	-2.4%	-5.5%	4.9%	3.1%	0	0
14-Sep-2022	5.93	219.18	12134.4	0.3%	1.2%	0.8%	-0.5%	0.4%	0	0
15-Sep-2022	5.95	220.64	11927.49	0.3%	0.7%	-1.7%	2.0%	2.4%	0	0
16-Sep-2022	5.99	218.11	11861.38	0.7%	-1.1%	-0.6%	1.2%	-0.6%	0	0
19-Sep-2022	5.71	216.89	11953.28	-4.7%	-0.6%	0.8%	-5.4%	-1.3%	0	0
20-Sep-2022	5.62	207.18	11851.54	-1.6%	-4.5%	-0.9%	-0.7%	-3.6%	0	0
21-Sep-2022	5.33	205.57	11637.79	-5.2%	-0.8%	-1.8%	-3.4%	1.0%	0	0
22-Sep-2022	5.27	207.98	11501.65	-1.1%	1.2%	-1.2%	0.0%	2.3%	0	0
23-Sep-2022	5.28	207.62	11311.24	0.2%	-0.2%	-1.7%	1.8%	1.5%	0	0
26-Sep-2022	5.32	203.3	11254.11	0.8%	-2.1%	-0.5%	1.3%	-1.6%	0	0
27-Sep-2022	5.46	205.89	11271.75	2.6%	1.3%	0.2%	2.5%	1.1%	0	0
28-Sep-2022	5.53	211.08	11493.83	1.3%	2.5%	2.0%	-0.7%	0.6%	0	0
29-Sep-2022	5.3	207.94	11164.78	-4.2%	-1.5%	-2.9%	-1.3%	1.4%	0	0
30-Sep-2022	5.44	209.38	10971.22	2.6%	0.7%	-1.7%	4.4%	2.4%	0	0
03-Oct-2022	5.52	213.93	11229.73	1.5%	2.2%	2.4%	-0.9%	-0.2%	0	0
04-Oct-2022	5.72	215.62	11582.54	3.6%	0.8%	3.1%	0.5%	-2.4%	0	0
05-Oct-2022	5.58	212.05	11573.18	-2.4%	-1.7%	-0.1%	-2.4%	-1.6%	0	0
06-Oct-2022	5.54	209.8	11485.5	-0.7%	-1.1%	-0.8%	0.0%	-0.3%	0	0
07-Oct-2022	5.44	206.77	11039.47	-1.8%	-1.4%	-3.9%	2.1%	2.4%	0	0
10-Oct-2022	5.28	205.95	10926.97	-2.9%	-0.4%	-1.0%	-1.9%	0.6%	0	0
11-Oct-2022	5.42	211.48	10791.35	2.7%	2.7%	-1.2%	3.9%	3.9%	0	0
12-Oct-2022	5.37	211.25	10785.62	-0.9%	-0.1%	-0.1%	-0.9%	-0.1%	0	0
13-Oct-2022	5.55	213.76	11033.58	3.4%	1.2%	2.3%	1.1%	-1.1%	0	0
14-Oct-2022	5.33	216.44	10692.06	-4.0%	1.3%	-3.1%	-0.9%	4.3%	0	0
17-Oct-2022	5.5	221.98	11062.53	3.2%	2.6%	3.5%	-0.3%	-0.9%	0	0
18-Oct-2022	5.29	219.38	11147.74	-3.8%	-1.2%	0.8%	-4.6%	-1.9%	0	0
19-Oct-2022	5.14	216.59	11103.38	-2.8%	-1.3%	-0.4%	-2.4%	-0.9%	0	0
20-Oct-2022	5.09	215.85	11046.71	-1.0%	-0.3%	-0.5%	-0.5%	0.2%	0	0
21-Oct-2022	4.9	219.3	11310.33	-3.7%	1.6%	2.4%	-6.1%	-0.8%	0	0
24-Oct-2022	4.75	222.09	11430.26	-3.1%	1.3%	1.1%	-4.1%	0.2%	0	0
25-Oct-2022	4.93	226.76	11669.99	3.8%	2.1%	2.1%	1.7%	0.0%	0	0
26-Oct-2022	5.02	227.7	11405.9	1.8%	0.4%	-2.3%	4.1%	2.7%	0	0
27-Oct-2022	4.84	225.81	11191.63	-3.6%	-0.8%	-1.9%	-1.7%	1.0%	0	0
28-Oct-2022	5.06	232.15	11546.21	4.5%	2.8%	3.2%	1.4%	-0.4%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
31-Oct-2022	4.89	230.53	11405.57	-3.4%	-0.7%	-1.2%	-2.1%	0.5%	0	0
01-Nov-2022	5.18	228.39	11288.95	5.9%	-0.9%	-1.0%	7.0%	0.1%	0	0
02-Nov-2022	4.99	253.65	10906.34	-3.7%	11.1%	-3.4%	-0.3%	14.4%	0	1
03-Nov-2022	5.12	265.42	10690.6	2.6%	4.6%	-2.0%	4.6%	6.6%	0	1
04-Nov-2022	5.02	264.69	10857.03	-2.0%	-0.3%	1.6%	-3.5%	-1.8%	0	0
07-Nov-2022	4.94	266.8	10977	-1.6%	0.8%	1.1%	-2.7%	-0.3%	0	0
08-Nov-2022	4.96	262.84	11059.5	0.4%	-1.5%	0.8%	-0.3%	-2.2%	0	0
09-Nov-2022	4.98	264.41	10797.55	0.4%	0.6%	-2.4%	2.8%	3.0%	0	0
10-Nov-2022	4.89	263.38	11605.96	-1.8%	-0.4%	7.5%	-9.3%	-7.9%	0	1
11-Nov-2022	4.92	255.45	11817.01	0.6%	-3.0%	1.8%	-1.2%	-4.8%	0	1
14-Nov-2022	4.92	254.64	11700.94	0.0%	-0.3%	-1.0%	1.0%	0.7%	0	0
15-Nov-2022	4.87	259.12	11871.15	-1.0%	1.8%	1.5%	-2.5%	0.3%	0	0
16-Nov-2022	4.77	261.05	11699.09	-2.1%	0.7%	-1.4%	-0.6%	2.2%	0	0
17-Nov-2022	4.68	264.75	11676.86	-1.9%	1.4%	-0.2%	-1.7%	1.6%	0	0
18-Nov-2022	4.68	264.62	11677.02	0.0%	0.0%	0.0%	0.0%	-0.1%	0	0
21-Nov-2022	4.77	265.59	11553.45	1.9%	0.4%	-1.1%	3.0%	1.4%	0	0
22-Nov-2022	4.8	270.93	11724.84	0.6%	2.0%	1.5%	-0.9%	0.5%	0	0
23-Nov-2022	4.89	266.86	11838.72	1.9%	-1.5%	1.0%	0.9%	-2.5%	0	0
25-Nov-2022	4.99	268.07	11756.03	2.0%	0.5%	-0.7%	2.7%	1.2%	0	0
28-Nov-2022	4.88	270.69	11587.75	-2.2%	1.0%	-1.4%	-0.8%	2.4%	0	0
29-Nov-2022	4.84	271.03	11503.45	-0.8%	0.1%	-0.7%	-0.1%	0.9%	0	0
30-Nov-2022	5.02	279.89	12030.06	3.7%	3.3%	4.6%	-0.9%	-1.3%	0	0
01-Dec-2022	5.31	275.61	12041.9	5.8%	-1.5%	0.1%	5.7%	-1.6%	0	0
02-Dec-2022	5.49	278.55	11994.26	3.4%	1.1%	-0.4%	3.8%	1.5%	0	0
05-Dec-2022	5.18	273.72	11786.8	-5.6%	-1.7%	-1.7%	-3.9%	0.0%	0	0
06-Dec-2022	5.42	276.6	11549.69	4.6%	1.1%	-2.0%	6.6%	3.1%	0	0
07-Dec-2022	5.54	277.08	11497.39	2.2%	0.2%	-0.5%	2.7%	0.6%	0	0
08-Dec-2022	5.66	279.88	11637.5	2.2%	1.0%	1.2%	0.9%	-0.2%	0	0
09-Dec-2022	5.65	280.43	11563.33	-0.2%	0.2%	-0.6%	0.5%	0.8%	0	0
12-Dec-2022	6.32	280.01	11706.44	11.9%	-0.1%	1.2%	10.6%	-1.4%	0	0
13-Dec-2022	6.54	276.43	11834.21	3.5%	-1.3%	1.1%	2.4%	-2.4%	0	0
14-Dec-2022	6.24	276.71	11740.92	-4.6%	0.1%	-0.8%	-3.8%	0.9%	0	0
15-Dec-2022	6.18	275.85	11345.22	-1.0%	-0.3%	-3.4%	2.4%	3.1%	0	0
16-Dec-2022	5.94	278.96	11243.72	-3.9%	1.1%	-0.9%	-3.0%	2.0%	0	0
19-Dec-2022	5.86	271.65	11084.59	-1.3%	-2.6%	-1.4%	0.1%	-1.2%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
20-Dec-2022	6.24	274.05	11072.43	6.5%	0.9%	-0.1%	6.6%	1.0%	0	0
21-Dec-2022	6.22	273.75	11235.88	-0.3%	-0.1%	1.5%	-1.8%	-1.6%	0	0
22-Dec-2022	6.24	277.25	10956.14	0.3%	1.3%	-2.5%	2.8%	3.8%	0	0
23-Dec-2022	6.17	278.82	10985.45	-1.1%	0.6%	0.3%	-1.4%	0.3%	0	0
27-Dec-2022	6.05	273.75	10822.51	-1.9%	-1.8%	-1.5%	-0.5%	-0.3%	0	0
28-Dec-2022	6.18	273.36	10679.35	2.1%	-0.1%	-1.3%	3.5%	1.2%	0	0
29-Dec-2022	6.48	275.99	10951.05	4.9%	1.0%	2.5%	2.3%	-1.6%	0	0
30-Dec-2022	6.37	278.09	10939.76	-1.7%	0.8%	-0.1%	-1.6%	0.9%	0	0
03-Jan-2023	6.09	273.32	10862.64	-4.4%	-1.7%	-0.7%	-3.7%	-1.0%	0	0
04-Jan-2023	6.06	272.83	10914.8	-0.5%	-0.2%	0.5%	-1.0%	-0.7%	0	0
05-Jan-2023	6.16	274.12	10741.22	1.7%	0.5%	-1.6%	3.2%	2.1%	0	0
06-Jan-2023	5.72	276.17	11040.35	-7.1%	0.7%	2.8%	-9.9%	-2.0%	0	0
09-Jan-2023	5.79	264.97	11108.45	1.2%	-4.1%	0.6%	0.6%	-4.7%	0	1
10-Jan-2023	6.03	263.41	11205.78	4.1%	-0.6%	0.9%	3.3%	-1.5%	0	0
11-Jan-2023	6.17	263.79	11402.53	2.3%	0.1%	1.8%	0.6%	-1.6%	0	0
12-Jan-2023	6.49	261.56	11459.61	5.2%	-0.8%	0.5%	4.7%	-1.3%	0	0
13-Jan-2023	6.45	261.04	11541.48	-0.6%	-0.2%	0.7%	-1.3%	-0.9%	0	0
17-Jan-2023	6.44	261.1	11557.19	-0.2%	0.0%	0.1%	-0.3%	-0.1%	0	0
18-Jan-2023	6.44	259.56	11410.29	0.0%	-0.6%	-1.3%	1.3%	0.7%	0	0
19-Jan-2023	6.35	260.02	11295.67	-1.4%	0.2%	-1.0%	-0.4%	1.2%	0	0
20-Jan-2023	6.42	261.7	11619.03	1.1%	0.6%	2.9%	-1.8%	-2.2%	0	0
23-Jan-2023	6.47	258.84	11872.54	0.8%	-1.1%	2.2%	-1.4%	-3.3%	0	0
24-Jan-2023	6.91	260.42	11846.65	6.8%	0.6%	-0.2%	7.0%	0.8%	0	0
25-Jan-2023	6.94	265.92	11814.69	0.4%	2.1%	-0.3%	0.7%	2.4%	0	0
26-Jan-2023	6.76	264.23	12051.48	-2.6%	-0.6%	2.0%	-4.6%	-2.6%	0	0
27-Jan-2023	6.68	259.68	12166.6	-1.2%	-1.7%	1.0%	-2.1%	-2.7%	0	0
30-Jan-2023	6.29	258.71	11912.39	-5.8%	-0.4%	-2.1%	-3.7%	1.7%	0	0
31-Jan-2023	6.6	263.17	12101.93	4.9%	1.7%	1.6%	3.3%	0.1%	0	0
01-Feb-2023	6.39	259.99	12363.1	-3.2%	-1.2%	2.2%	-5.3%	-3.4%	0	0
02-Feb-2023	7.01	259.48	12803.14	9.7%	-0.2%	3.6%	6.1%	-3.8%	0	0
03-Feb-2023	7.13	252.8	12573.36	1.7%	-2.6%	-1.8%	3.5%	-0.8%	0	0
06-Feb-2023	6.9	255.24	12464.52	-3.2%	1.0%	-0.9%	-2.4%	1.8%	0	0
07-Feb-2023	6.97	255.65	12728.27	1.0%	0.2%	2.1%	-1.1%	-2.0%	0	0
08-Feb-2023	6.86	252.77	12495.38	-1.6%	-1.1%	-1.8%	0.3%	0.7%	0	0
09-Feb-2023	6.84	253.24	12381.17	-0.3%	0.2%	-0.9%	0.6%	1.1%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
10-Feb-2023	6.87	255.11	12304.92	0.4%	0.7%	-0.6%	1.1%	1.4%	0	0
13-Feb-2023	6.93	256	12502.31	0.9%	0.3%	1.6%	-0.7%	-1.3%	0	0
14-Feb-2023	6.96	253.14	12590.89	0.4%	-1.1%	0.7%	-0.3%	-1.8%	0	0
15-Feb-2023	7.03	253.36	12687.89	1.0%	0.1%	0.8%	0.2%	-0.7%	0	0
16-Feb-2023	7.91	251.45	12442.48	12.5%	-0.8%	-1.9%	14.5%	1.2%	1	0
17-Feb-2023	7.83	255.76	12358.19	-1.0%	1.7%	-0.7%	-0.3%	2.4%	0	0
21-Feb-2023	7.45	255.25	12060.3	-4.9%	-0.2%	-2.4%	-2.4%	2.2%	0	0
22-Feb-2023	7.48	243.75	12066.27	0.4%	-4.5%	0.0%	0.4%	-4.6%	0	1
23-Feb-2023	7.63	248.36	12180.14	2.0%	1.9%	0.9%	1.1%	0.9%	0	0
24-Feb-2023	7.48	249.76	11969.65	-2.0%	0.6%	-1.7%	-0.2%	2.3%	0	0
27-Feb-2023	7.56	246.93	12057.79	1.1%	-1.1%	0.7%	0.3%	-1.9%	0	0
28-Feb-2023	7.57	246.04	12042.12	0.1%	-0.4%	-0.1%	0.3%	-0.2%	0	0
01-Mar-2023	7.43	244.89	11938.57	-1.8%	-0.5%	-0.9%	-1.0%	0.4%	0	0
02-Mar-2023	7.18	244.76	12044.87	-3.4%	-0.1%	0.9%	-4.3%	-0.9%	0	0
03-Mar-2023	7.34	248.69	12290.81	2.2%	1.6%	2.0%	0.2%	-0.4%	0	0
06-Mar-2023	7.3	248.02	12302.48	-0.5%	-0.3%	0.1%	-0.6%	-0.4%	0	0
07-Mar-2023	7.03	236.77	12152.17	-3.7%	-4.5%	-1.2%	-2.5%	-3.3%	0	0
08-Mar-2023	7.02	222.64	12215.33	-0.1%	-6.0%	0.5%	-0.7%	-6.5%	0	1
09-Mar-2023	6.64	225.26	11995.88	-5.4%	1.2%	-1.8%	-3.6%	3.0%	0	0
10-Mar-2023	6.16	228.77	11830.28	-7.2%	1.6%	-1.4%	-5.8%	2.9%	0	0
13-Mar-2023	6.49	224.72	11923.17	5.4%	-1.8%	0.8%	4.6%	-2.6%	0	0
14-Mar-2023	6.52	220.66	12199.79	0.5%	-1.8%	2.3%	-1.9%	-4.1%	0	0
15-Mar-2023	6.36	217.5	12251.32	-2.5%	-1.4%	0.4%	-2.9%	-1.9%	0	0
16-Mar-2023	7.33	220.05	12581.39	15.3%	1.2%	2.7%	12.6%	-1.5%	1	0
17-Mar-2023	7.22	219.73	12519.88	-1.5%	-0.1%	-0.5%	-1.0%	0.3%	0	0
20-Mar-2023	7.1	225.11	12562.61	-1.7%	2.4%	0.3%	-2.0%	2.1%	0	0
21-Mar-2023	7.2	222.33	12741.44	1.4%	-1.2%	1.4%	0.0%	-2.7%	0	0
22-Mar-2023	6.86	212.99	12567.15	-4.7%	-4.2%	-1.4%	-3.4%	-2.8%	0	0
23-Mar-2023	6.89	216.02	12729.23	0.4%	1.4%	1.3%	-0.9%	0.1%	0	0
24-Mar-2023	6.85	219.94	12767.05	-0.6%	1.8%	0.3%	-0.9%	1.5%	0	0
27-Mar-2023	6.87	218.01	12673.07	0.3%	-0.9%	-0.7%	1.0%	-0.1%	0	0
28-Mar-2023	6.8	218.92	12610.57	-1.0%	0.4%	-0.5%	-0.5%	0.9%	0	0
29-Mar-2023	6.98	217.23	12846.03	2.6%	-0.8%	1.9%	0.8%	-2.6%	0	0
30-Mar-2023	6.74	219	12963.14	-3.4%	0.8%	0.9%	-4.4%	-0.1%	0	0
31-Mar-2023	6.91	223.96	13181.35	2.5%	2.3%	1.7%	0.8%	0.6%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
03-Apr-2023	7.04	225.32	13148.35	1.9%	0.6%	-0.3%	2.1%	0.9%	0	0
04-Apr-2023	6.93	227.18	13100.08	-1.6%	0.8%	-0.4%	-1.2%	1.2%	0	0
05-Apr-2023	6.73	232.99	12967.2	-2.9%	2.6%	-1.0%	-1.9%	3.6%	0	0
06-Apr-2023	6.75	227.19	13062.6	0.3%	-2.5%	0.7%	-0.4%	-3.2%	0	0
10-Apr-2023	6.74	223.07	13051.23	-0.1%	-1.8%	-0.1%	-0.1%	-1.7%	0	0
11-Apr-2023	6.74	226.3	12964.16	0.0%	1.4%	-0.7%	0.7%	2.1%	0	0
12-Apr-2023	6.67	225.8	12848.35	-1.0%	-0.2%	-0.9%	-0.1%	0.7%	0	0
13-Apr-2023	6.91	231.72	13109.39	3.6%	2.6%	2.0%	1.6%	0.6%	0	0
14-Apr-2023	6.76	228.72	13079.52	-2.2%	-1.3%	-0.2%	-1.9%	-1.1%	0	0
17-Apr-2023	7.01	230.35	13087.71	3.7%	0.7%	0.1%	3.6%	0.6%	0	0
18-Apr-2023	6.98	227.98	13091.79	-0.4%	-1.0%	0.0%	-0.5%	-1.1%	0	0
19-Apr-2023	7	226.68	13088.72	0.3%	-0.6%	0.0%	0.3%	-0.5%	0	0
20-Apr-2023	6.78	225.17	12985.98	-3.1%	-0.7%	-0.8%	-2.4%	0.1%	0	0
21-Apr-2023	6.94	230.76	13000.77	2.4%	2.5%	0.1%	2.2%	2.4%	0	0
24-Apr-2023	6.8	228.29	12969.76	-2.0%	-1.1%	-0.2%	-1.8%	-0.8%	0	0
25-Apr-2023	6.7	226.31	12725.11	-1.5%	-0.9%	-1.9%	0.4%	1.0%	0	0
26-Apr-2023	6.76	225.87	12806.49	0.9%	-0.2%	0.6%	0.3%	-0.8%	0	0
27-Apr-2023	6.66	227.71	13160.03	-1.5%	0.8%	2.8%	-4.2%	-1.9%	0	0
28-Apr-2023	6.71	230.13	13245.99	0.8%	1.1%	0.7%	0.1%	0.4%	0	0
01-May-2023	6.68	232.11	13231.47	-0.4%	0.9%	-0.1%	-0.3%	1.0%	0	0
02-May-2023	6.63	228.79	13113.66	-0.7%	-1.4%	-0.9%	0.1%	-0.5%	0	0
03-May-2023	7.05	218.4	13030.21	6.3%	-4.5%	-0.6%	7.0%	-3.9%	0	0
04-May-2023	7.32	215.72	12982.48	3.8%	-1.2%	-0.4%	4.2%	-0.9%	0	0
05-May-2023	7.4	214.12	13259.13	1.1%	-0.7%	2.1%	-1.0%	-2.9%	0	0
08-May-2023	7.6	210.46	13291.64	2.7%	-1.7%	0.2%	2.5%	-2.0%	0	0
09-May-2023	7.6	209.6	13201.11	0.0%	-0.4%	-0.7%	0.7%	0.3%	0	0
10-May-2023	7.47	212.24	13347.83	-1.7%	1.3%	1.1%	-2.8%	0.1%	0	0
11-May-2023	7.26	213.48	13389.78	-2.8%	0.6%	0.3%	-3.1%	0.3%	0	0
12-May-2023	7.36	214.02	13340.18	1.4%	0.3%	-0.4%	1.7%	0.6%	0	0
15-May-2023	7.4	214.4	13413.51	0.5%	0.2%	0.5%	0.0%	-0.4%	0	0
16-May-2023	7.51	212.05	13426.01	1.5%	-1.1%	0.1%	1.4%	-1.2%	0	0
17-May-2023	7.81	216.19	13589.26	4.0%	2.0%	1.2%	2.8%	0.7%	0	0
18-May-2023	7.82	216.79	13834.62	0.1%	0.3%	1.8%	-1.7%	-1.5%	0	0
19-May-2023	8.3	219.56	13803.49	6.1%	1.3%	-0.2%	6.4%	1.5%	0	0
22-May-2023	8.49	218.59	13849.74	2.3%	-0.4%	0.3%	2.0%	-0.8%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
23-May-2023	8.51	216.19	13672.54	0.2%	-1.1%	-1.3%	1.5%	0.2%	0	0
24-May-2023	8.58	214.09	13604.48	0.8%	-1.0%	-0.5%	1.3%	-0.5%	0	0
25-May-2023	8.745	212.14	13938.53	1.9%	-0.9%	2.5%	-0.5%	-3.4%	0	0
26-May-2023	8.35	207.32	14298.41	-4.5%	-2.3%	2.6%	-7.1%	-4.9%	0	1
30-May-2023	7.94	205.19	14354.99	-4.9%	-1.0%	0.4%	-5.3%	-1.4%	0	0
31-May-2023	8.12	209.74	14254.09	2.3%	2.2%	-0.7%	3.0%	2.9%	0	0
01-Jun-2023	8.63	213.48	14441.51	6.3%	1.8%	1.3%	5.0%	0.5%	0	0
02-Jun-2023	8.89	217.22	14546.64	3.0%	1.8%	0.7%	2.3%	1.0%	0	0
05-Jun-2023	8.78	218.88	14556.5	-1.2%	0.8%	0.1%	-1.3%	0.7%	0	0
06-Jun-2023	8.59	220.25	14558.09	-2.2%	0.6%	0.0%	-2.2%	0.6%	0	0
07-Jun-2023	8.485	220.66	14303.29	-1.2%	0.2%	-1.8%	0.5%	1.9%	0	0
08-Jun-2023	8.53	226.5	14484.54	0.5%	2.6%	1.3%	-0.7%	1.4%	0	0
09-Jun-2023	8.41	228.49	14528.36	-1.4%	0.9%	0.3%	-1.7%	0.6%	0	0
12-Jun-2023	8.17	227.9	14784.3	-2.9%	-0.3%	1.8%	-4.6%	-2.0%	0	0
13-Jun-2023	8.22	229.53	14900.85	0.6%	0.7%	0.8%	-0.2%	-0.1%	0	0
14-Jun-2023	7.87	226.28	15005.69	-4.3%	-1.4%	0.7%	-5.0%	-2.1%	0	0
15-Jun-2023	8.27	229.59	15185.48	5.1%	1.5%	1.2%	3.9%	0.3%	0	0
16-Jun-2023	8.63	230.26	15083.92	4.4%	0.3%	-0.7%	5.0%	1.0%	0	0
20-Jun-2023	9.06	223.4	15070.15	5.0%	-3.0%	-0.1%	5.1%	-2.9%	0	0
21-Jun-2023	9.41	223.07	14867.45	3.9%	-0.1%	-1.3%	5.2%	1.2%	0	0
22-Jun-2023	9.43	225.23	15042.32	0.2%	1.0%	1.2%	-1.0%	-0.2%	0	0
23-Jun-2023	9	222.36	14891.48	-4.6%	-1.3%	-1.0%	-3.6%	-0.3%	0	0
26-Jun-2023	8.99	220.78	14689.02	-0.1%	-0.7%	-1.4%	1.2%	0.6%	0	0
27-Jun-2023	8.92	215.12	14945.91	-0.8%	-2.6%	1.7%	-2.5%	-4.3%	0	0
28-Jun-2023	9.9	214.8	14964.58	11.0%	-0.1%	0.1%	10.9%	-0.3%	0	0
29-Jun-2023	8.15	219.79	14939.95	-17.7%	2.3%	-0.2%	-17.5%	2.5%	1	0
30-Jun-2023	7.85	220.75	15179.21	-3.7%	0.4%	1.6%	-5.3%	-1.2%	0	0
03-Jul-2023	7.825	223.75	15208.69	-0.3%	1.4%	0.2%	-0.5%	1.2%	0	0
05-Jul-2023	7.92	219.43	15203.78	1.2%	-1.9%	0.0%	1.2%	-1.9%	0	0
06-Jul-2023	7.63	213	15089.45	-3.7%	-2.9%	-0.8%	-2.9%	-2.2%	0	0
07-Jul-2023	7.71	211.82	15036.85	1.0%	-0.6%	-0.3%	1.4%	-0.2%	0	0
10-Jul-2023	7.71	223.14	15045.64	0.0%	5.3%	0.1%	-0.1%	5.3%	0	1
11-Jul-2023	7.7	221.65	15119.06	-0.1%	-0.7%	0.5%	-0.6%	-1.2%	0	0
12-Jul-2023	7.71	229.91	15307.23	0.1%	3.7%	1.2%	-1.1%	2.5%	0	0
13-Jul-2023	8	229.81	15571.98	3.8%	0.0%	1.7%	2.0%	-1.8%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
14-Jul-2023	7.85	232	15565.6	-1.9%	1.0%	0.0%	-1.8%	1.0%	0	0
17-Jul-2023	7.73	234.26	15713.28	-1.5%	1.0%	0.9%	-2.5%	0.0%	0	0
18-Jul-2023	7.82	237.91	15841.35	1.2%	1.6%	0.8%	0.3%	0.7%	0	0
19-Jul-2023	7.92	242.19	15826.35	1.3%	1.8%	-0.1%	1.4%	1.9%	0	0
20-Jul-2023	8.05	244.34	15466.09	1.6%	0.9%	-2.3%	3.9%	3.2%	0	0
21-Jul-2023	8.15	248.24	15425.67	1.2%	1.6%	-0.3%	1.5%	1.9%	0	0
24-Jul-2023	7.11	245.73	15448.02	-12.8%	-1.0%	0.1%	-12.9%	-1.2%	1	0
25-Jul-2023	7.065	244.6	15561.42	-0.6%	-0.5%	0.7%	-1.4%	-1.2%	0	0
26-Jul-2023	7.055	242.84	15499.27	-0.1%	-0.7%	-0.4%	0.3%	-0.3%	0	0
27-Jul-2023	7.31	242.77	15464.93	3.6%	0.0%	-0.2%	3.8%	0.2%	0	0
28-Jul-2023	7.76	245.17	15750.93	6.2%	1.0%	1.8%	4.3%	-0.9%	0	0
31-Jul-2023	7.72	242.72	15757	-0.5%	-1.0%	0.0%	-0.6%	-1.0%	0	0
01-Aug-2023	7.8	240.13	15718.01	1.0%	-1.1%	-0.2%	1.3%	-0.8%	0	0
02-Aug-2023	7.82	240.85	15370.74	0.3%	0.3%	-2.2%	2.5%	2.5%	0	0
03-Aug-2023	7.895	231.87	15353.54	1.0%	-3.7%	-0.1%	1.1%	-3.6%	0	0
04-Aug-2023	8.11	236.37	15274.92	2.7%	1.9%	-0.5%	3.2%	2.5%	0	0
07-Aug-2023	7.75	237.8	15407.85	-4.4%	0.6%	0.9%	-5.3%	-0.3%	0	0
08-Aug-2023	7.64	236.78	15273.05	-1.4%	-0.4%	-0.9%	-0.5%	0.4%	0	0
09-Aug-2023	7.65	235.01	15101.71	0.1%	-0.7%	-1.1%	1.3%	0.4%	0	0
10-Aug-2023	7.89	237.15	15128.84	3.1%	0.9%	0.2%	3.0%	0.7%	0	0
11-Aug-2023	7.17	237.8	15028.07	-9.1%	0.3%	-0.7%	-8.5%	0.9%	0	0
14-Aug-2023	7.02	233.26	15205.59	-2.1%	-1.9%	1.2%	-3.3%	-3.1%	0	0
15-Aug-2023	6.97	235.73	15037.65	-0.7%	1.1%	-1.1%	0.4%	2.2%	0	0
16-Aug-2023	6.92	230.77	14876.47	-0.7%	-2.1%	-1.1%	0.4%	-1.0%	0	0
17-Aug-2023	6.77	228.12	14715.81	-2.2%	-1.1%	-1.1%	-1.1%	-0.1%	0	0
18-Aug-2023	6.96	229.8	14694.84	2.8%	0.7%	-0.1%	2.9%	0.9%	0	0
21-Aug-2023	6.8	231.14	14936.69	-2.3%	0.6%	1.6%	-3.9%	-1.1%	0	0
22-Aug-2023	6.83	231.06	14908.96	0.4%	0.0%	-0.2%	0.6%	0.2%	0	0
23-Aug-2023	6.89	231.46	15148.06	0.9%	0.2%	1.6%	-0.7%	-1.4%	0	0
24-Aug-2023	7	230.53	14816.44	1.6%	-0.4%	-2.2%	3.8%	1.8%	0	0
25-Aug-2023	7.08	229.01	14941.83	1.1%	-0.7%	0.8%	0.3%	-1.5%	0	0
28-Aug-2023	7.1	226.01	15052.46	0.3%	-1.3%	0.7%	-0.5%	-2.1%	0	0
29-Aug-2023	7.09	229.53	15376.55	-0.1%	1.6%	2.2%	-2.3%	-0.6%	0	0
30-Aug-2023	7.02	228.44	15462.43	-1.0%	-0.5%	0.6%	-1.5%	-1.0%	0	0
31-Aug-2023	6.87	224.36	15501.07	-2.1%	-1.8%	0.2%	-2.4%	-2.0%	0	0

## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
01-Sep-2023	7	228.05	15490.86	1.9%	1.6%	-0.1%	2.0%	1.7%	0	0
05-Sep-2023	6.99	225.23	15508.24	-0.1%	-1.2%	0.1%	-0.3%	-1.3%	0	0
06-Sep-2023	6.85	223.36	15371.44	-2.0%	-0.8%	-0.9%	-1.1%	0.1%	0	0
07-Sep-2023	7.09	222.63	15258.52	3.5%	-0.3%	-0.7%	4.2%	0.4%	0	0
08-Sep-2023	7.08	225.13	15280.23	-0.1%	1.1%	0.1%	-0.3%	1.0%	0	0
11-Sep-2023	7.06	225.32	15461.87	-0.3%	0.1%	1.2%	-1.5%	-1.1%	0	0
12-Sep-2023	7.02	223.78	15289.74	-0.6%	-0.7%	-1.1%	0.5%	0.4%	0	0
13-Sep-2023	6.95	222.34	15348.53	-1.0%	-0.6%	0.4%	-1.4%	-1.0%	0	0
14-Sep-2023	6.83	219.49	15473.89	-1.7%	-1.3%	0.8%	-2.5%	-2.1%	0	0
15-Sep-2023	6.45	220.24	15202.4	-5.6%	0.3%	-1.8%	-3.8%	2.1%	0	0
18-Sep-2023	6.47	217.48	15225.37	0.3%	-1.3%	0.2%	0.2%	-1.4%	0	0
19-Sep-2023	6.48	220.67	15191.23	0.2%	1.5%	-0.2%	0.4%	1.7%	0	0
20-Sep-2023	6.28	223.93	14969.92	-3.1%	1.5%	-1.5%	-1.6%	2.9%	0	0
21-Sep-2023	6.41	223.68	14694.24	2.1%	-0.1%	-1.8%	3.9%	1.7%	0	0
22-Sep-2023	6.385	222.75	14701.1	-0.4%	-0.4%	0.0%	-0.4%	-0.5%	0	0
25-Sep-2023	6.27	224.06	14768.9	-1.8%	0.6%	0.5%	-2.3%	0.1%	0	0
26-Sep-2023	6.31	229.91	14545.83	0.6%	2.6%	-1.5%	2.1%	4.1%	0	0
27-Sep-2023	6.39	232.47	14580.16	1.3%	1.1%	0.2%	1.0%	0.9%	0	0
28-Sep-2023	6.35	226.03	14702.77	-0.6%	-2.8%	0.8%	-1.5%	-3.6%	0	0
29-Sep-2023	6.34	225.87	14715.24	-0.2%	-0.1%	0.1%	-0.2%	-0.2%	0	0
02-Oct-2023	6.23	222.14	14837.57	-1.7%	-1.7%	0.8%	-2.6%	-2.5%	0	0
03-Oct-2023	6.33	221.49	14565.62	1.6%	-0.3%	-1.8%	3.4%	1.5%	0	0
04-Oct-2023	6.43	221.93	14776.25	1.6%	0.2%	1.4%	0.1%	-1.2%	0	0
05-Oct-2023	6.92	228.29	14723.22	7.6%	2.9%	-0.4%	8.0%	3.2%	0	0
06-Oct-2023	6.62	234.34	14973.24	-4.3%	2.7%	1.7%	-6.0%	1.0%	0	0
09-Oct-2023	6.58	231.11	15047.16	-0.6%	-1.4%	0.5%	-1.1%	-1.9%	0	0
10-Oct-2023	6.51	230.33	15131.52	-1.1%	-0.3%	0.6%	-1.6%	-0.9%	0	0
11-Oct-2023	6.44	234.58	15241.12	-1.1%	1.8%	0.7%	-1.8%	1.1%	0	0
12-Oct-2023	6.17	232.2	15184.1	-4.2%	-1.0%	-0.4%	-3.8%	-0.6%	0	0
13-Oct-2023	6.16	233.16	14995.12	-0.2%	0.4%	-1.2%	1.1%	1.7%	0	0
16-Oct-2023	6.1	232.9	15172.73	-1.0%	-0.1%	1.2%	-2.2%	-1.3%	0	0
17-Oct-2023	6.11	236.77	15122.01	0.2%	1.7%	-0.3%	0.5%	2.0%	0	0
18-Oct-2023	5.86	230.31	14909.26	-4.1%	-2.7%	-1.4%	-2.7%	-1.3%	0	0
19-Oct-2023	5.77	225.82	14783.13	-1.5%	-1.9%	-0.8%	-0.7%	-1.1%	0	0
20-Oct-2023	6.165	225.43	14560.88	6.8%	-0.2%	-1.5%	8.3%	1.3%	0	0



## Exhibit 5.2

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
23-Oct-2023	6.12	224.15	14604.85	-0.7%	-0.6%	0.3%	-1.0%	-0.9%	0	0
24-Oct-2023	6.395	227.23	14745.86	4.5%	1.4%	1.0%	3.5%	0.4%	0	0
25-Oct-2023	6.27	224.5	14381.64	-2.0%	-1.2%	-2.5%	0.5%	1.3%	0	0
26-Oct-2023	6.31	224.4	14109.57	0.6%	0.0%	-1.9%	2.5%	1.8%	0	0
27-Oct-2023	6.2	219.23	14180.42	-1.7%	-2.3%	0.5%	-2.2%	-2.8%	0	0
30-Oct-2023	6.24	220.63	14335.51	0.6%	0.6%	1.1%	-0.4%	-0.5%	0	0
31-Oct-2023	6.51	222.86	14409.78	4.3%	1.0%	0.5%	3.8%	0.5%	0	0
01-Nov-2023	6.59	224.08	14664.91	1.2%	0.5%	1.8%	-0.5%	-1.2%	0	0
02-Nov-2023	6.46	228.18	14919.55	-2.0%	1.8%	1.7%	-3.7%	0.1%	0	0
03-Nov-2023	6.65	224.43	15099.49	2.9%	-1.6%	1.2%	1.7%	-2.8%	0	0
06-Nov-2023	6.56	228.18	15154.93	-1.4%	1.7%	0.4%	-1.7%	1.3%	0	0
07-Nov-2023	6.8	230.44	15296.02	3.7%	1.0%	0.9%	2.7%	0.1%	0	0
08-Nov-2023	6.495	225.73	15313.24	-4.5%	-2.0%	0.1%	-4.6%	-2.2%	0	0
09-Nov-2023	6.13	221.72	15187.9	-5.6%	-1.8%	-0.8%	-4.8%	-1.0%	0	0
10-Nov-2023	6.27	222.84	15529.12	2.3%	0.5%	2.2%	0.0%	-1.7%	0	0
13-Nov-2023	6.325	225.34	15482.79	0.9%	1.1%	-0.3%	1.2%	1.4%	0	0
14-Nov-2023	6.38	228.38	15812.47	0.9%	1.3%	2.1%	-1.3%	-0.8%	0	0
15-Nov-2023	6.43	229.26	15817.18	0.8%	0.4%	0.0%	0.8%	0.4%	0	0
16-Nov-2023	6.31	226.63	15833.17	-1.9%	-1.1%	0.1%	-2.0%	-1.2%	0	0
17-Nov-2023	6.33	228.94	15837.99	0.3%	1.0%	0.0%	0.3%	1.0%	0	0
20-Nov-2023	6.5	228.99	16027.06	2.7%	0.0%	1.2%	1.5%	-1.2%	0	0
21-Nov-2023	6.6	230.43	15933.62	1.5%	0.6%	-0.6%	2.1%	1.2%	0	0
22-Nov-2023	6.72	230.48	16001.39	1.8%	0.0%	0.4%	1.4%	-0.4%	0	0
24-Nov-2023	6.85	231.13	15982.01	1.9%	0.3%	-0.1%	2.1%	0.4%	0	0
27-Nov-2023	6.87	231.1	15961.98	0.3%	0.0%	-0.1%	0.4%	0.1%	0	0
28-Nov-2023	7.07	230.39	16010.43	2.9%	-0.3%	0.3%	2.6%	-0.6%	0	0
29-Nov-2023	7.14	232.07	15987.6	1.0%	0.7%	-0.1%	1.1%	0.9%	0	0
30-Nov-2023	7.16	240	15947.87	0.3%	3.4%	-0.2%	0.5%	3.7%	0	0
01-Dec-2023	7.27	240.73	15997.58	1.5%	0.3%	0.3%	1.2%	0.0%	0	0
04-Dec-2023	7.42	239.94	15839.67	2.1%	-0.3%	-1.0%	3.1%	0.7%	0	0
05-Dec-2023	6.9	240.31	15877.71	-7.0%	0.2%	0.2%	-7.2%	-0.1%	0	0
06-Dec-2023	7.18	239.98	15788.05	4.1%	-0.1%	-0.6%	4.6%	0.4%	0	0
07-Dec-2023	7.2	242.07	16022.49	0.3%	0.9%	1.5%	-1.2%	-0.6%	0	0
08-Dec-2023	7.23	241.65	16084.69	0.4%	-0.2%	0.4%	0.0%	-0.6%	0	0
11-Dec-2023	7.16	244.86	16221.74	-1.0%	1.3%	0.9%	-1.8%	0.5%	0	0

## Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
12-Dec-2023	7.24	251.7	16354.25	1.1%	2.8%	0.8%	0.3%	2.0%	0	0
13-Dec-2023	7.15	256.94	16562.37	-1.2%	2.1%	1.3%	-2.5%	0.8%	0	0
14-Dec-2023	7.29	254.09	16537.83	2.0%	-1.1%	-0.1%	2.1%	-1.0%	0	0
15-Dec-2023	7.45	246.45	16623.45	2.2%	-3.0%	0.5%	1.7%	-3.5%	0	0
18-Dec-2023	7.465	246.4	16729.8	0.2%	0.0%	0.6%	-0.4%	-0.7%	0	0
19-Dec-2023	7.885	240.26	16811.86	5.6%	-2.5%	0.5%	5.1%	-3.0%	0	0
20-Dec-2023	10.7	225.51	16554.16	35.7%	-6.1%	-1.5%	37.2%	-4.6%	1	1
21-Dec-2023	11.27	218.27	16757.41	5.3%	-3.2%	1.2%	4.1%	-4.4%	0	1
22-Dec-2023	11.77	218.93	16777.4	4.4%	0.3%	0.1%	4.3%	0.2%	0	0
26-Dec-2023	11.62	216.27	16878.46	-1.3%	-1.2%	0.6%	-1.9%	-1.8%	0	0
27-Dec-2023	12.19	214.88	16906.8	4.9%	-0.6%	0.2%	4.7%	-0.8%	0	0
28-Dec-2023	12.07	219.24	16898.47	-1.0%	2.0%	0.0%	-0.9%	2.1%	0	0
29-Dec-2023	12.03	219.89	16825.93	-0.3%	0.3%	-0.4%	0.1%	0.7%	0	0
02-Jan-2024	11.53	227.35	16543.94	-4.2%	3.4%	-1.7%	-2.5%	5.1%	0	1
03-Jan-2024	11.35	228.18	16368.49	-1.6%	0.4%	-1.1%	-0.5%	1.4%	0	0
04-Jan-2024	12.255	230.11	16282.01	8.0%	0.8%	-0.5%	8.5%	1.4%	0	0
05-Jan-2024	12.66	229.4	16305.98	3.3%	-0.3%	0.1%	3.2%	-0.5%	0	0
08-Jan-2024	12.86	231.04	16649.87	1.6%	0.7%	2.1%	-0.5%	-1.4%	0	0
09-Jan-2024	13.17	224.36	16678.7	2.4%	-2.9%	0.2%	2.2%	-3.1%	0	0
10-Jan-2024	12.63	221.66	16793.05	-4.1%	-1.2%	0.7%	-4.8%	-1.9%	0	0
11-Jan-2024	12.5	220.3	16820.9	-1.0%	-0.6%	0.2%	-1.2%	-0.8%	0	0
12-Jan-2024	12.44	219.05	16832.92	-0.5%	-0.6%	0.1%	-0.6%	-0.6%	0	0
16-Jan-2024	12.38	218.72	16830.71	-0.5%	-0.2%	0.0%	-0.5%	-0.1%	0	0
17-Jan-2024	13.43	222.25	16736.28	8.5%	1.6%	-0.6%	9.0%	2.2%	0	0
18-Jan-2024	13.34	219.11	16982.29	-0.7%	-1.4%	1.5%	-2.1%	-2.9%	0	0
19-Jan-2024	12.89	217.84	17314.01	-3.4%	-0.6%	2.0%	-5.3%	-2.5%	0	0
22-Jan-2024	13.03	216.24	17330.38	1.1%	-0.7%	0.1%	1.0%	-0.8%	0	0
23-Jan-2024	12.25	217.79	17404.21	-6.0%	0.7%	0.4%	-6.4%	0.3%	0	0
24-Jan-2024	12.06	218.81	17499.3	-1.6%	0.5%	0.5%	-2.1%	-0.1%	0	0
25-Jan-2024	11.97	219.32	17516.99	-0.7%	0.2%	0.1%	-0.8%	0.1%	0	0
26-Jan-2024	12.17	218.01	17421.01	1.7%	-0.6%	-0.5%	2.2%	0.0%	0	0
29-Jan-2024	12.51	216.91	17596.27	2.8%	-0.5%	1.0%	1.8%	-1.5%	0	0
30-Jan-2024	12.61	215.02	17476.71	0.8%	-0.9%	-0.7%	1.5%	-0.2%	0	0
31-Jan-2024	12.78	214.78	17137.24	1.3%	-0.1%	-1.9%	3.3%	1.8%	0	0
01-Feb-2024	13.6	215.97	17344.71	6.4%	0.6%	1.2%	5.2%	-0.7%	0	0

Stock Price Data

Exchange Date	Closing Price			1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX	LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR
02-Feb-2024	13.58	213.41	17642.73	-0.1%	-1.2%	1.7%	-1.9%	-2.9%	0	0
05-Feb-2024	13.54	212.76	17613.04	-0.3%	-0.3%	-0.2%	-0.1%	-0.1%	0	0
06-Feb-2024	13.54	214.95	17572.73	0.0%	1.0%	-0.2%	0.2%	1.3%	0	0
07-Feb-2024	14.58	210.76	17755.07	7.7%	-1.9%	1.0%	6.6%	-3.0%	0	0
08-Feb-2024	14.68	211.74	17783.17	0.7%	0.5%	0.2%	0.5%	0.3%	0	0
09-Feb-2024	14.81	212.34	17962.41	0.9%	0.3%	1.0%	-0.1%	-0.7%	0	0
12-Feb-2024	15.06	216.25	17882.66	1.7%	1.8%	-0.4%	2.1%	2.3%	0	0
13-Feb-2024	14.31	213.75	17600.42	-5.0%	-1.2%	-1.6%	-3.4%	0.4%	0	0
14-Feb-2024	14.8	214.43	17807.63	3.4%	0.3%	1.2%	2.2%	-0.9%	0	0
15-Feb-2024	14.83	214.54	17845.72	0.2%	0.1%	0.2%	0.0%	-0.2%	0	0
16-Feb-2024	14.59	214.73	17685.98	-1.6%	0.1%	-0.9%	-0.7%	1.0%	0	0
20-Feb-2024	14.13	214.16	17546.1	-3.2%	-0.3%	-0.8%	-2.4%	0.5%	0	0
21-Feb-2024	14.255	219.18	17478.91	0.9%	2.3%	-0.4%	1.3%	2.7%	0	0
22-Feb-2024	14.04	217.6	18004.7	-1.5%	-0.7%	3.0%	-4.5%	-3.7%	0	0
23-Feb-2024	14.32	227.03	17937.61	2.0%	4.3%	-0.4%	2.4%	4.7%	0	1
26-Feb-2024	14.62	223.58	17933.33	2.1%	-1.5%	0.0%	2.1%	-1.5%	0	0
27-Feb-2024	14.69	226.75	17971.05	0.5%	1.4%	0.2%	0.3%	1.2%	0	0
28-Feb-2024	14.385	227.28	17874.5	-2.1%	0.2%	-0.5%	-1.5%	0.8%	0	0
29-Feb-2024	14.16	225.64	18043.85	-1.6%	-0.7%	0.9%	-2.5%	-1.7%	0	0
01-Mar-2024	14.52	231.92	18302.91	2.5%	2.8%	1.4%	1.1%	1.3%	0	0
04-Mar-2024	13.69	228.74	18226.48	-5.7%	-1.4%	-0.4%	-5.3%	-1.0%	0	0
05-Mar-2024	13.79	229.81	17897.87	0.7%	0.5%	-1.8%	2.5%	2.3%	0	0
06-Mar-2024	13.63	236.97	18017.58	-1.2%	3.1%	0.7%	-1.8%	2.4%	0	0
07-Mar-2024	13.66	239.96	18297.99	0.2%	1.3%	1.6%	-1.3%	-0.3%	0	0
08-Mar-2024	14.04	243.05	18018.45	2.8%	1.3%	-1.5%	4.3%	2.8%	0	0

	LQDA	UTHR
mean	0.1%	0.0%
sd	0.0560	0.0219
n	1180	1180
2 st dev: lower bound	-11.07%	-4.36%
2 st dev: upper bound	11.33%	4.41%

Stock Price Data

Exchange Date	Closing Price				1-Day Change			Normalized Price Change		Flag: 2 st devs from mean	
	LQDA	UTHR	NDX		LQDA	UTHR	NDX	LQDA	UTHR	LQDA	UTHR

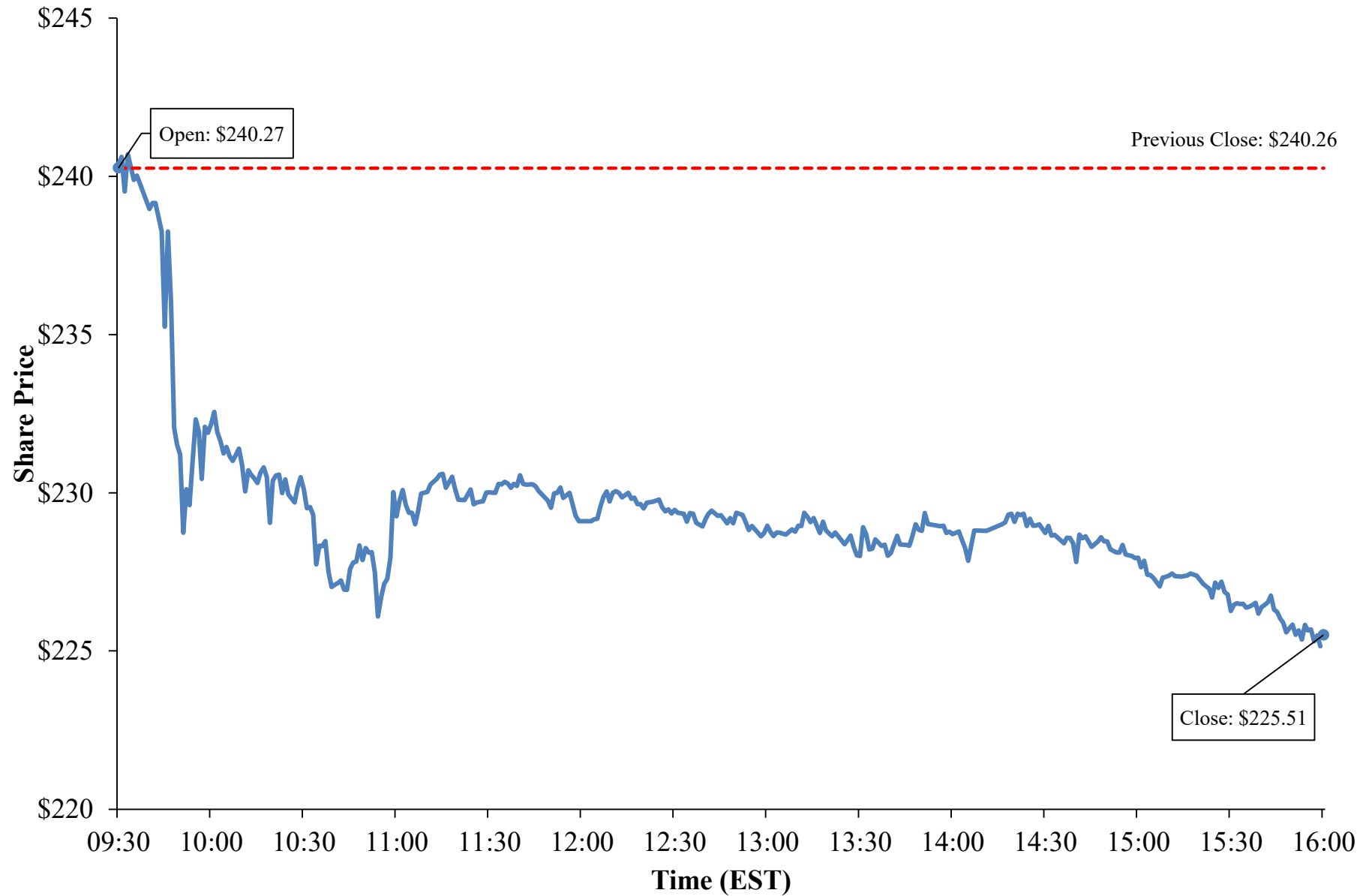
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Source:

Thompson Reuters Eikon Stock Price Data

**Exhibit 6**

**UTHR Intraday Price, 20 December 2023**



*Source: Price data from Thomson Reuters.*

### **CERTIFICATE OF SERVICE**

I hereby certify that on April 26, 2024, the foregoing document was  
Filed using the Court's CM/ECF system, which will send notice of such filing to  
all registered CM/ECF users.

/s/ Sanya Sukduang

Sanya Sukduang  
COOLEY LLP

### **CERTIFICATE OF COMPLIANCE**

The foregoing filing complies with the type-volume limitation of Federal Rule of Appellate Procedure 27(d) and 32(a) and has been prepared using a proportionally-spaced typeface and includes 5,185 words.

Dated: April 26, 2024

/s/ Sanya Sukduang

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